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Evaluating the Impact of the Guatemalan Nursing Program on Staff, Organizational, and Clinical Outcomes

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Evaluating the Impact of the Guatemalan Nursing Program on Staff, Organizational, and Clinical Outcomes

Abstract

There is great disparity between the outcome of childhood cancer in developed and developing countries. Nurses, who comprise the largest group of health care professionals globally, are essential to successful treatment. Pediatric oncology education is generally unavailable for nurses in developing countries. This lack of education is likely to contribute to the disparity in survival rates, as undereducated nurses are unable to meet the demands of pediatric cancer care. A second critical problem in developing countries is the workload of the nurse, with a patient nurse ratio reported as high as 30 patients per one nurse.

In 2006, the quality of nursing care at St. Jude Children's Research Hospital's partner site in Guatemala was assessed using standards from six Joint Commission International quality domains. Although quality standards were found lacking in all six domains, the most critical needs with relevance to nursing were identified in the domain of Staff Qualifications and Education. To meet this need, the Guatemalan Nursing Program (GNP) was developed. Because of the critical needs determined by the assessment, the primary focus of the program was improving nursing education and staffing. A secondary focus was on improving all quality standards with relevance to nursing.

This research study was designed to evaluate the GNP's fidelity and impact on staff, organizational, and clinical outcomes. Staff and organizational outcomes were evaluated using a before and after one group design often used in program evaluation. The clinical outcomes were evaluated using a control site comparison but no randomization and was therefore a quasi-experimental design. Variables analyzed included staff variables of continuing education hours, chemotherapy competency, central venous line care competency, and completion of pediatric oncology nursing education course for newly hired nurses, organizational variables of Joint Commission International standards and patient to nurse ratio, and clinical variables of event free survival and abandonment. Logic model theory provided the conceptual framework for both the development and evaluation of the GNP.

This study substantiated that prior to GNP implementation a lack of education for pediatric oncology nurses existed in Guatemala and demonstrated that a nurse educator can positively impact staff outcomes related to pediatric oncology education. The GNP also positively affected organizational outcomes. Compared to pre program results, the number of Joint Commission International standards met post program increased considerably. In 2006, the patient to nurse ratio was 6 to 8 (average 7) patients per nurse and in 2009, the patient to nurse ratio was 4 to 6 (average 5) patients per nurse. The study found a statistically significant association with an improved CIN of treatment abandonment within the first year of diagnosis. Abandonment of treatment is a critical problem in developing countries. Although many studies have looked at abandonment and its causes; no study has looked at the specific effect of nursing interventions on abandonment. The study did not find an association with improved EFS. However, pediatric oncology patients who abandon treatment die, thus an improvement in abandonment should in time result in improved survival.

Nursing research in developing countries is limited, resulting in unique opportunities to conduct many "first time" studies. Today all components of the health care system are expected to demonstrate their value, and accountability is an important expectation of the health care system. This is even a greater need in developing countries where nursing is given little value and support. Nursing policies that dictate patient to nurse ratios and funding of new nursing positions are determined by the Ministry of Health in most developing countries. Empirical evidence is needed justify changes in policy. Evidence that education and improved staffing impact clinical outcomes has the potential of providing an impetus for a change in nursing policy.

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**EVALUATING THE IMPACT OF THE GUATEMALAN NURSING PROGRAM
ON STAFF, ORGANIZATIONAL, AND CLINICAL OUTCOMES**

A Dissertation
Presented for
The Graduate Studies Council
The University of Tennessee
Health Science Center

In Partial Fulfillment
Of the Requirements for the Degree
Doctor of Philosophy
From The University of Tennessee

By
Sara Williamson Day
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ABSTRACT

There is great disparity between the outcome of childhood cancer in developed and developing countries. Nurses, who comprise the largest group of health care professionals globally, are essential to successful treatment. Pediatric oncology education is generally unavailable for nurses in developing countries. This lack of education is likely to contribute to the disparity in survival rates, as undereducated nurses are unable to meet the demands of pediatric cancer care. A second critical problem in developing countries is the workload of the nurse, with a patient nurse ratio reported as high as 30 patients per one nurse.

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This research study was designed to evaluate the GNP's fidelity and impact on staff, organizational, and clinical outcomes. Staff and organizational outcomes were evaluated using a before and after one group design often used in program evaluation. The clinical outcomes were evaluated using a control site comparison but no randomization and was therefore a quasi-experimental design. Variables analyzed included staff variables of continuing education hours, chemotherapy competency, central venous line care competency, and completion of pediatric oncology nursing education course for newly hired nurses, organizational variables of Joint Commission International standards and patient to nurse ratio, and clinical variables of event free survival and abandonment. Logic model theory provided the conceptual framework for both the development and evaluation of the GNP.

This study substantiated that prior to GNP implementation a lack of education for pediatric oncology nurses existed in Guatemala and demonstrated that a nurse educator can positively impact staff outcomes related to pediatric oncology education. The GNP also positively affected organizational outcomes. Compared to pre program results, the number of Joint Commission International standards met post program increased considerably. In 2006, the patient to nurse ratio was 6 to 8 (average 7) patients per nurse and in 2009, the patient to nurse ratio was 4 to 6 (average 5) patients per nurse. The study found a statistically significant association with an improved CIN of treatment abandonment within the first year of diagnosis. Abandonment of treatment is a critical problem in developing countries. Although many studies have looked at abandonment and its causes; no study has looked at the specific effect of nursing interventions on abandonment. The study did not find an association with improved EFS. However,

pediatric oncology patients who abandon treatment die, thus an improvement in abandonment should in time result in improved survival.

Nursing research in developing countries is limited, resulting in unique opportunities to conduct many “first time” studies. Today all components of the health care system are expected to demonstrate their value, and accountability is an important expectation of the health care system. This is even a greater need in developing countries where nursing is given little value and support. Nursing policies that dictate patient to nurse ratios and funding of new nursing positions are determined by the Ministry of Health in most developing countries. Empirical evidence is needed justify changes in policy. Evidence that education and improved staffing impact clinical outcomes has the potential of providing an impetus for a change in nursing policy.

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CHAPTER 1. INTRODUCTION

Overview

There is great disparity between the outcome of childhood cancer in developed and developing countries. As a group, pediatric cancers are curable; the 5-year survival rate is 80% in the United States and Western Europe (Jemal et al., 2006). In developing countries, however, the 5-year survival rate is often less than 20% (Barr et al., 2006). One of the key principles of successful treatment of childhood cancer is the provision of specialized professional care in pediatric cancer units (Wagner & Antic, 1997; McGregor, Metzger, Sanders, & Santana, 2007). Nurses, who comprise the largest group of health care professionals globally, are essential to successful treatment. Quality pediatric oncology nursing care requires advanced knowledge and clinical skills. Expert pediatric oncology nursing care requires skills based on extensive knowledge of pediatric cancer. Pediatric oncology nurses play a major role in managing disease-related complications, coordinating care for central venous lines, and administering chemotherapy (Hockenberry & Kline, 2006). Most hospitals in developed countries provide extensive education and training to newly hired pediatric oncology nurses and require that they complete a chemotherapy certification course before administering chemotherapy (Hockenberry & Kline, 2006). In contrast, pediatric oncology education and training is generally unavailable for nurses in developing countries. This lack of education is likely to contribute to the disparity in survival rates, as undereducated nurses are unable to meet the demands of pediatric cancer care (Wilimas et al., 2003; Barr et al., 2006). A second critical problem in developing countries is the workload of the nurse, with a patient nurse ratio reported as high as 30 patients per one nurse. Recent large-scale studies have demonstrated that inadequate nurse staffing results in longer hospital stays, increased risk for complications, and an increase in mortality (Aiken, Clarke, & Sloane, 2002; Buerhaus, Mattke, Stewart, & Zelevinsky, 2002; Aiken, Clarke, Sloane, Lake, & Cheney, 2008). All pediatric oncology patients are considered high acuity because of the scope and frequency of care required (Hockenberry & Kline, 2006); the patient to nurse ratio of 4 to 1 is recommended for intermediate care areas and 2 to 1 is recommended for critical care areas.

In 2006, the quality of nursing care at St. Jude Children's Research Hospital's (St. Jude) partner site in Guatemala was assessed using standards from six Joint Commission International quality domains. Although quality standards were found lacking in all six domains, the most critical needs with relevance to nursing were identified in the domain of Staff Qualifications and Education. After careful review of the quality assessment and discussions with St. Jude and Guatemalan leaders, it was agreed that a nursing program to improve the quality of nursing care provided to pediatric oncology patients in Guatemala would be developed and implemented. Because of the critical needs determined by the assessment, the primary focus of the program was improving nursing education and staffing. A secondary focus was on improving all quality standards with relevance to nursing; however, it was understood that this would be a longer term goal. This research study was designed to evaluate the Guatemalan Nursing Program's (GNP) fidelity and impact on staff, organizational, and clinical outcomes.

Background

International Outreach Nursing History

The International Outreach Program (IOP) at St. Jude was established to improve the worldwide survival rate of children with cancer and other catastrophic illnesses by transferring knowledge and technology to partner sites established in developing countries. When the IOP began in 1993, a lack of nurses with pediatric oncology skills was a major impediment to the implementation of the partnership programs in Latin America. The first efforts to educate nurses consisted of a short (1 to 2 weeks) series of lectures taught at the partner site by St. Jude nurses. As the IOP program grew and gained partner sites, more extensive education programs were needed. In 1998, the IOP established the International Training Center for Pediatric Oncology Nurses in San Salvador, El Salvador in partnership with the Salvadoran Society of Professional Nurses and the Benjamin Bloom Hospital, a multispecialty children's hospital. The residential school offered a 12-week course in theory and clinical practice and was open to all pediatric oncology nurses from Latin American partner site countries. After 4 years of operation several concerns resulted in a decision to close the school. The cost of operating the school was more than the proposed budget, and many nurses could not attend the school because they were not able to commit to 12 weeks away from home (Wilimas et al., 2003).

Nursing Program Development

In 2006, a new approach was taken and a comprehensive International Outreach Nursing Program was developed. Carty and White (1996) used a strategic planning model in developing a general education program for Nicaraguan nurses. The authors found that a strategic plan was essential for developing a successful program in the complex process of international nursing education. A strategic planning model was also used to provide an organized framework for the International Outreach Nursing program. A mission statement and goals designed to synergistically support the mission were developed. The program's mission is to provide the highest quality of nursing care to patients and families in the IOP's partner sites. The program's goals include: (a) assessing the quality of nursing care and developing a process for improving the quality of care; (b) providing comprehensive pediatric oncology education and skills training to nursing staff; (c) developing strong partnerships with nursing leaders and educators affiliated with international nursing; and (d) contributing to the international nursing body of knowledge through research. The nursing program has been implemented in partner sites in Guatemala, El Salvador, Chile, Columbia, Mexico, and Shanghai. This research study will focus on Guatemala, where the program was initially implemented (Day, Dycus, Chismark & McKeon, 2008).

Partner-Site and Nursing Overview

The partner-site in Guatemala City, Guatemala was opened in 2000 with financial support from the country's Ministry of Health, a local non-governmental philanthropic foundation, and St. Jude. The pediatric oncology unit, the site affiliated with St. Jude, functions independently within a much larger public hospital system. The inpatient facility includes intensive care, intermediate care, isolation and general care units, totaling 37 beds. The outpatient facility includes a procedure room and a day hospital with 4 exam rooms and 10 beds. Approximately 1000 patients are treated annually, and both units average a 95 to 100% occupancy rate. Most parents stay throughout the hospitalization and assist with their child's care. Nursing personnel include a head nurse and assistant head nurse for each inpatient unit and for the outpatient day hospital and professional and technical staff nurses. The head nurse is responsible for management of three service divisions: nursing, housekeeping, and administrative support. The head nurse's management responsibilities include supervision, hiring, orientation, and evaluation of staff in all three divisions. In addition, the head nurse assumes the role of staff nurse when necessary. The assistant head nurses are responsible for direct supervision of nurses on the unit and coordinating staffing schedules. The responsibilities of the professional nurse include: physical assessment and evaluation, direct patient care, patient and family education, medication administration, staff education, and administrative duties. The responsibilities of the technical nurse include: obtaining vital signs, recording intake and output, providing direct care in accordance with the patient's condition, and administering medication including chemotherapy. The educational preparation of professional nurses includes three years of training in a university or independent nursing school setting. The curriculum content is similar to that of nursing programs in the United States, and post-graduate nursing courses are offered at one university in the area. Preparation of technical nurses includes 10 to 12 months of training at an educational facility.

Preliminary Studies: Nursing Assessment

The initial step of program implementation included a comprehensive assessment of the quality of nursing care. Standards of nursing care and professional performance were evaluated in Guatemala using standards endorsed by Joint Commission International, (JCI) a division of the Joint Commission on Accreditation of Healthcare Organizations. Joint Commission International standards are universally recognized as the gold standard for international accreditation and were developed to assess quality and safety of healthcare in a wide variety of health care settings (Joint Commission International, Joint Commission International Accreditation Standards for hospitals, 2007). The standards take into account that hospitals in many developing countries do not yet function at the level of U.S. hospital standards; and therefore, are less stringent in evaluation criteria (Marshall et al., 2006). The standards have been adapted for the international community and designed to be culturally applicable and compliant with laws and regulations outside the United States (Timmons, 2007). A set of standards this broad in nature cannot account for a country's unique characteristics; however, there is

evidence that many quality concerns are universal. Aiken, Clarke, and Sloane (2002) noted that countries tend to believe problems with quality of care and nurse staffing are a result of unique circumstances. Yet, data from their study suggested that contrary to popular opinion many hospital problems know no country boundaries.

Nursing quality was assessed using JCI's six quality domains: Access to Care and Continuity of Care; Assessment of Patients; Care of Patients; Patient and Family Education; Prevention and Control of Infections; and Staff Qualifications and Education. Only those standards with relevance to nursing were selected, and standards were evaluated from a nursing perspective. The methods used to complete the evaluation included direct observation of nursing care and a review of medical records, policies, procedures, and job descriptions. Interviews with nursing staff and a tour of the site were also conducted. Findings are summarized by JCI domains.

Access to Care and Continuity of Care

Patient data were available for all healthcare providers to access and included the patient record and an up-to-date Kardex containing the data relevant to nursing care. Communication of patient information was observed during a nursing shift report. There was no evidence of a written nursing care plan. There was a process in place for patient transfer including specific data to report to the receiving nurse. Multidisciplinary rounds were not observed or reported as part of standard practice. Communication between the nurses and physicians appeared minimal.

Assessment of Patients

Evidence of an initial nursing admission assessment was non-existent, and there was no initial assessment documentation form. The head nurse stated that assessments were required each shift and were documented on an assessment flow sheet. Although the assessment flow sheet was not consistently completed, all charts reviewed contained daily nursing notes. Vital signs were assessed and documented every hour in ICU and every 3 hours on all other units. Nurses indicated time limitations as the major factor preventing the documentation of assessments each shift (Day et al., 2008).

Care of Patients

Policies and procedures for the care of high-risk patients were not available. There were no written policies for administering chemotherapy, nor were there formal training and competency assessment requirements for nurses who administer chemotherapy. Chemotherapy was not always administered by a professional nurse, and there were many occasions when a technical nurse administered chemotherapy. Medications were stored on carts and refrigerators in the patient hallway. Nurses reported that the patient was identified by checking the patient identification armband prior to

administering medications and performing treatments. Most medications were prepared in the pharmacy and were safely labeled. Some intravenous medications were prepared by the nurses. There was no policy in place to guide the medication process; nor was there a policy for reporting medication errors (Day et al., 2008).

Patient and Family Education

One professional nurse was dedicated to the role of patient and family education. The education program focused on newly diagnosed patients and their families. The nurse provided home visits to patients and families who needed extensive teaching. The educational needs, education provided, or the preferred learning style of the patients and families were not documented.

Prevention and Control of Infections

One professional nurse was designated as the infection control nurse; she had been trained on the job to perform her responsibilities. She supervised intravenous line care, application of isolation measures, registration of nosocomial infections, and management of the biosafety program. The unit had isolation rooms to help prevent the spread of communicable disease and to isolate vulnerable patients. Due to space constraints, the rooms on the general unit were semi-private, a known risk factor for immunocompromised patients. All units were clean and housekeeping personnel were observed constantly cleaning all patient care and communal areas. The nurses reported difficulty obtaining antibacterial soap and alcohol gel. One technical nurse, assigned to obtaining patient vital signs, was observed going from patient to patient without washing her hands or using alcohol gel between patient contacts. This practice is a known risk for hospital acquired infections among patients (Day et al., 2008).

Staff Qualifications and Education

A staffing plan to confirm patient nurse staffing ratios was not available. There was no evidence that assignments were based on scope and frequency of care required and skill level of the nurse. According to staff interviews and direct observation in the general care unit, the nurses were each assigned from 6 to 8 patients for the day shift. Nursing job descriptions defining specific responsibilities were available, though the human resources director, the hospital administrator, and the nursing director were currently revising them.

Pediatric oncology nursing education (orientation program) for newly hired nurses consisted of a 15-day trial period without pay. During this time the nurse spent time with another pediatric oncology staff nurse. There was currently no structured pediatric oncology nursing education program for newly hired nurses in place, and no one was designated to ensure that the new nurse received adequate education. The

responsibility of education fell on whoever was available at the time, and often the assistant head nurse or a staff nurse assumed the responsibility. Also, there was no mechanism to ensure that the new nurse was competent after orientation was completed. Furthermore, there was no systematic process for chemotherapy education.

The head nurse stated that continuing education included lectures directed at topics relevant to nursing but lectures occurred infrequently. Competencies were not evaluated when a new nurse was hired and annual competencies were not done. Personnel files did not contain any documentation of education and there were no other records documenting education. No records were available to document nurse turnover rates, but the staff said nurses often left the partner-site to work at hospitals with better salaries (Day et al., 2008).

Nursing Interview

A nursing meeting was conducted to discuss nursing issues and concerns. The head nurse, assistant nurses from inpatient and outpatient units, the patient educator, and infection control nurse attended. Overall, the meeting was very positive and focused on initiatives needed to improve nursing care. The nurses displayed a high commitment to their patients, emphasizing that their primary goal was to ensure the provision of excellent patient care. The following comments expressed during the meeting clearly conveyed their dedication: “The working conditions need improvement but I will not leave.”; “I can’t describe adequately why I stay, but something inside me will not let me leave.”; “The desire to care for these children is a part of my life.”; and “I could be paid more somewhere else, but I do not want to leave.” During this meeting the nurses identified four major barriers to providing quality care: excessive patient load, lack of essential equipment, need for further professional education, and a perceived lack of respect from physicians which hindered morale.

Recommendations

The nursing quality assessment provided the baseline from which nursing needs and recommendations were determined. The overall objective was to restore the nursing program at the foundational level, not to build one from scratch. The foremost challenge was to prioritize areas of need and provide recommendations that could be realistically implemented. After careful review of the findings and discussions with St. Jude and Guatemalan leaders, it was agreed that a nursing program to improve the quality of nursing care provided to pediatric oncology patients in Guatemala would be developed and implemented. The assessment findings clearly documented a critical need for pediatric oncology nursing education and improved staffing. Because of the critical needs determined by the assessment, the primary focus of the program was to improve nursing education and staffing. A secondary focus was on improving all quality standards with relevance to nursing; however, it was understood that this would be a longer term goal.

Significance of the Study

Cancer in children in developing countries is a matter of increasing importance for public health worldwide. The relative importance of childhood cancer in developing countries is increasing due to the overall improvement in child health and the reduction in the incidence and mortality from communicable diseases (Barr et al., 2006). To close the survival gap between the outcome of childhood cancer in developed and developing countries provision of care in pediatric cancer units by specialized professionals is needed (Wagner & Antic, 1997; McGregor et al., 2007). Nurses comprise the largest group of health care providers in pediatric oncology in developing countries, yet specialized education and training is generally not available for these nurses and is potentially one of the reasons for the disparity in survival rates (Wilimas et al., 2003). In addition the patient to nurse ratio is much higher than recommended for pediatric oncology nursing care (Day et al., 2008). Whether this disparity in survival rates could be attenuated through a nursing program designed to provide specialized pediatric oncology education and improved staffing levels is unknown. Research consisting of a systematic assessment of the process (fidelity) and outcomes of the Guatemalan Nursing Program is needed to answer this question. Process will be assessed to determine if the program has been implemented as designed, and outcomes will be measured to determine the effects of the program on staff, organizational, and clinical outcomes.

This research was the first study to examine the effects of staff education and nurse staffing levels on patient outcomes in the pediatric oncology population in a developing country, and therefore has the potential to contribute to nursing's scientific body of knowledge. The impact of nursing education on patient outcomes has been extensively researched in developed countries. Several recent large scale studies in the United States and Canada have suggested that staff education contributes to patient outcomes such as mortality (Aiken, Clarke, Cheung, Sloane, & Silber, 2003; Elixhauser, Steiner, & Fraser, 2003; Estabrooks, Midodzi, Cummings, Ricker, & Giovannetti, 2005). Aiken and colleagues (2003) demonstrated that in hospitals with higher proportions of nurses educated at the baccalaureate level, surgical patients experienced lower mortality and failure-to-rescue rates. Estabrooks and colleagues (2005) also demonstrated that hospitals with a higher proportion of baccalaureate-prepared nurses were associated with lower rates of 30-day patient mortality. Studies conducted in developing countries to assess the effect of staff education on patient mortality are limited; however, a study in Zambia showed that a 6 month training course for nurse midwives was associated with a decrease in early neonatal mortality rates (Chomba, 2008).

The effect of nurse staffing levels on patient outcomes has also been well researched in developed countries. A systematic review of research on the relationship between nurse staffing and patient outcomes commissioned by the Agency of Healthcare Quality and Research concluded that a strong evidence base links better nurse staffing to better patient outcomes (Kane, Shamliyan, Mueller, Duval, & Witt, 2007). Although most research to assess the association between nurse staffing and patient outcomes has been conducted in US hospitals, studies in Canada (Estabrooks et al., 2005) and England

(Rafferty et al., 2007) have shown consistent results. To date, no studies have been conducted in developing countries.

Long term sustainability of this program is dependent on policy changes at the national level. Nursing policies that dictate patient to nurse ratios and funding of new nursing positions is determined by the Ministry of Health in Guatemala. Empirical evidence is needed to make changes in policy. Evidence that education and improved staffing impact clinical outcomes has the potential of providing an impetus for a change in nursing policy.

The value of nursing is not recognized in many developing countries. Interviews with medical and administrative leaders from IOP partner sites and assessment results support this conclusion (Day et al., 2008). This study has the potential to impact the professional role and identity of pediatric oncology nurses in Guatemala and affect the extent to which nursing's impact might be measured and valued.

In conclusion, this research study will be the first to examine the effects of nursing education and improved staffing on the clinical outcomes of patient survival and abandonment in the pediatric oncology population in a developing country. This study has the potential to contribute new evidence to nursing science, provide program sustainability by impacting policy, and promote the value of nursing.

Specific Aims

The primary purpose of this research study was to measure the impact of the GNP on staff, organizational, and clinical outcomes at the IOP's partner site in Guatemala. Staff aims included a comparison of the percentage of nurses hired post program implementation (on or after January 1, 2007) that successfully completed the pediatric oncology nursing education course for newly hired nurses, consisting of 5 days of documented presentations on the fundamentals of pediatric oncology and 5 days of clinical experience with a preceptor, to a benchmark expectation of 100% completion rate. A comparison of the mean annual hours of continuing education for year 2008 was compared to the annual continuing education hours required for pediatric oncology nurse certification by the Association of Pediatric Hematology/Oncology Nurses (APHON). The percentage of nurses competent in central venous line care, defined by documented central venous line course completion with an evaluation score of $\geq 70\%$, was compared to pre program implementation competency percentages. The percentage of nurses competent in chemotherapy administration, defined by documented chemotherapy course completion with an evaluation score of $\geq 70\%$, was compared to the pre program implementation percentages. Organizational aims included pre and post program comparisons of patient to nurse ratio and JCI standard evaluation results. Clinical aims included a pre and post program comparison of event free survival (EFS) distributions and cumulative incidence of treatment abandonment within the first year of diagnosis; comparisons were made within the intervention site (Guatemala) and to a control site (Honduras). Pre-program time period included patients diagnosed between January 01, 2004 and December 31, 2006, and post program included patients diagnosed between

January 01, 2007 and October 01, 2008. No patients registered in POND after the date of IRB approval (October 2009) were entered into the study; therefore, October 01, 2008 was chosen as the post program cutoff date to allow a full year of patient follow up. Patients included two groups, a heterogeneous group of all pediatric oncology patients and a more homogeneous group of only patients with acute lymphoblastic leukemia. According to Needleman and Buerhaus (2003) it is more likely that an association is observed between nurse staffing and mortality in subpopulations in which risk is more homogeneous.

Staff Specific Aims

- Compare the percentage of nurses hired post program implementation that successfully completed the Pediatric Oncology Education Program for newly hired nurses to the expectation of 100% completion rate.
- Compare the percentage of nurses who are competent in central venous line care to the pre program implementation percentage.
- Compare the percentage of nurses who are competent in chemotherapy administration to the pre program implementation percentage.
- Compare the mean annual hours of continuing education for year 2008 to the mean annual continuing education hours required for Association of Pediatric Hematology/Oncology Nurses (APHON) certification.

Organizational Specific Aims

- Compare the patient to nurse ratio pre program to post program.
- Compare the percentage of JCI nursing quality standards met pre program to post program.

Clinical Specific Aims

- Compare the pre and post program EFS distributions in Guatemala (with relapse or death classified as events) for all cancer patients and for acute lymphoblastic lymphoma patients (within site comparison).
- Compare the pre and post program EFS distributions for all cancer patients between the intervention site in Guatemala and the control site in Honduras (control site comparison).
- Compare the pre and post program EFS distributions for acute lymphoblastic

lymphoma patients between the intervention site in Guatemala and the control site in Honduras (control site comparison).

- Compare the pre and post program cumulative incidence (CIN) of treatment abandonment within the first year of diagnosis in Guatemala for all cancer patients and for acute lymphoblastic leukemia patients.
- Compare the pre and post program CIN of treatment abandonment within the first year of diagnosis for all cancer patients between the intervention site in Guatemala and the control site in Honduras (control site comparison).
- Compare the pre and post program CIN of treatment abandonment within the first year of diagnosis for patients with acute lymphoblastic leukemia between the intervention site in Guatemala and the control site in Honduras (control site comparison).

Conceptual Framework

According to program theorist Carolyn Weiss (1998), a program is a theory and the evaluation is its test. The program theory is a set of beliefs that underlie the action of the program. The beliefs that underlie this program include: implementation of a nursing intervention designed to improve nursing education and staffing will result in improved staff, organizational, and clinical outcomes at St. Jude's partner site in Guatemala. The conceptual model provides support for the selection of variables to be studied, the expected relationship between variables and the expected outcomes. This intervention study involved both process and outcome evaluation. Process evaluation measured the program's fidelity or how well the program was operationalized, and outcome evaluation determined the effects of the program for the intended beneficiaries (Weiss, 1998).

Logic model theory provided the conceptual framework for both the development and evaluation of the GNP. Logic model theory facilitates effective program development, implementation, and evaluation and provides a systematic way to present the relationship among resources, interventions, and program outcomes. The term "logic model" is often used interchangeably with the term "program theory". Logic models are referred to as theory because they describe the sequence of related events connecting the need for the planned program with the program's desired results. A conceptual model using the logic model framework illustrates the sequence of activities thought to bring about change and how these activities are linked to the results the program is expected to achieve (Logic Model Development Guide, 2001). A logic model links theoretical ideas together to explain underlying program hypotheses. The focus is on the problem or issue and the reasons for providing the solution (intervention) in your program approach. Conrad, Randolph, Kirby and Bebout (1999) noted that logic models assist in the evaluation process in several ways. They identify underlying program theory and provide a guide for organizing the process evaluation. In addition the model provides the structure for the fidelity of the program and provides a framework for the outcome evaluation.

Logic model theory has been used to guide the development and evaluation of health care programs for over 20 years. Support for the logic model comes from literature in several fields, including nursing. Several recent nursing studies used logic model theory as their framework. Dykeman, MacIntosh, Seaman, and Davidson (2003) used the Logic Model to measure the process and outcomes of a nurse-managed community health clinic. Hulton (2007) described how a logic model was used by school nurses in the development, implementation, and evaluation of a school-based program aimed to prevent teenage pregnancy. Most recently, the University of British Columbia School of Nursing in Vancouver used a logic model to build collaborative practice capacity between academic and practice partners (MacPhee, 2009).

The conceptual model for this study illustrates the sequence of program events, beginning with the initial needs assessment and concluding with the intended result at the highest level, the impact on patients with cancer. The model includes three broad domains, the intervention, implementation process, and program outcomes. The process evaluation to determine program fidelity included activities provided in the implementation domain: continuing education, chemotherapy classes, central venous line care classes, and pediatric oncology education program for newly hired nurses. The outcome evaluation includes both intermediate outcomes (staff and organizational) and long-term outcomes (event free survival and abandonment). The conceptual model is depicted in **Figure 1.1**, and concept definitions are included in **Table 1.1**.

Assumptions

The following were assumptions of the study:

- Staff nurses willingly and responsibly participate in education offered.
- Chemotherapy and central venous line care competency are concepts that can be measured.
- Nursing competency in chemotherapy and central venous line care contribute to improved survival and treatment abandonment.
- Pediatric oncology knowledge is a concept that can be measured using evaluation tests.
- The pediatric oncology nurse educator delivers education consistently to all nurses at the Guatemalan partner site.
- The effect of the nursing program can be measured separately from the effects of the practice organization and healthcare system.
- Clinical data is entered consistently into POND at both the intervention site and control site.

Figure 1.1 Conceptual Model Based on Logic Model Theory

Table 1.1 Concept Definitions

Concept Definition	
Guatemalan nursing program	A program developed at St. Jude's partner site in Guatemala City, Guatemala, to meet critical nursing needs determined by the JCI nursing assessment. The primary focus of the program was improving nursing education and staffing. A secondary focus was improving all nursing quality standards.
Pediatric oncology nurse educator	A professional nurse dedicated full time to implementing a pediatric oncology education program,, providing continuing education, teaching courses in chemotherapy administration and central venous line care skills, improving quality standards relevant to nursing, and serving as the IOP nursing liaison.
Staff nurse	A full time professional nurse who had worked for a minimum of six months at St. Jude's partner site at the National Unit of Pediatric Oncology in Guatemala City, Guatemala and was not in a management position.
Professional nurse	Graduation from a school of nursing (diploma or university degree) as documented by the hospital's human resources department.
Employed full time	Working ≥ 30 hours per week.
Continuing education hours	Documented attendance at an educational class. Education was documented in the nurse's education record and included title of class, length of time, and presenter.
Chemotherapy competency	Documented chemotherapy course completion in the nurse's education record. Documentation included course title, date, hours of course, presenter, and course evaluation score. A course evaluation score of $\geq 70\%$ was required for competency.
Central venous line care competency	Documented central venous line care course completion in the nurse's education record. Documentation included course title, date, hours of course, presenter, and course evaluation score. A course evaluation score of $\geq 70\%$ was required for competency.
Pediatric oncology education course for newly hired nurses	5 consecutive days of documented theoretical presentations and 5 consecutive days of documented clinical experience with a preceptor. An evaluation score of $\geq 70\%$ was required for successful completion of the course.
Event free survival	Patients who were alive without relapse at time of data collection.

Table 1.1 (Continued)

Concept Definition	
Abandonment of treatment	4 consecutive weeks of missed appointments during active cancer treatment.
Cancer	Patients diagnosed with acute lymphoblastic leukemia, acute myelogenous leukemia, neuroblastoma, hepatoblastoma, retinoblastoma, rhabdomyosarcoma, Hodgkin's disease, Non-Hodgkin's lymphoma, osteosarcoma, Ewing's sarcoma, Wilms tumor, and germ cell tumor

Limitations

The following were limitations of the study:

- Conducting research in a developing country with limited resources and cultural and language barriers was perhaps the greatest limitation of this study.
- Clinical endpoints for this research were abandonment of treatment and event free survival rate of children with cancer. Data for traditional nurse-sensitive measures, such as nosocomial infection rates, central line and chemotherapy complications, and pain management were not available, which was a limitation of this study.
- The nurse educator in Guatemala assumed the educator role in January 2007. The Latin American Center for Pediatric Oncology Nursing Education, designed to provide nurse educators with the education, resources, and professional support, was not operational until January 2008.
- The educator did not benefit from the Center's support initially, and this is a study limitation. However, during the educator's first year the IOP nursing director organized on site education and provided support and direction via bimonthly conference calls.
- Maturation was a potential threat to internal validity and therefore a limitation of this study. Maturation refers to the processes that occur within subjects as a result of the passage of time rather than the intervention. For example, the nurses could gain knowledge over the course of the study due to experience and maturity. However, pediatric oncology skills are highly specialized and not likely to be acquired without formal instruction.
- The intervention (the Guatemalan Nursing Program) experienced changes during the study's three year time span. In 2008, after the nurse educator completed the educator course offered by the Latin American Center for Pediatric Oncology

Nursing Education, the courses in pediatric oncology nursing education, chemotherapy administration, and the central venous line care were revised to include expanded content. In addition, the educator matured in his knowledge level and teaching skills during the course of the study.

- Staff nurse outcomes, specifically competency in chemotherapy administration and central venous line care were measured using assessment instruments developed by the nurse educator in Guatemala and the questions were based on the content taught. Content validity was assessed by nurse experts from the Latin American Center of Pediatric Oncology Nursing Education. Three nurses reviewed each question for relevance and clarity. The reviewers had access to the course content for reference. Revisions to several questions were made based on the review. A limitation to this study was the fact that the instruments were not rigorously assessed for content validity, and reliability testing was not done.

CHAPTER 2. LITERATURE REVIEW

A review of literature relevant to the major concepts in this study is included in this chapter. The first section addresses status of pediatric oncology nursing in developing countries. This study tested a cause and effect hypothesis, therefore an empirical relationship between the presumed cause (nursing program to improve education and staffing) and the presumed long term effects (improved survival and abandonment) must be established (Polit & Beck, 2008). Literature that supports a relationship between these concepts is provided in section two.

Pediatric Oncology Nursing in Developing Countries

In developed countries 80% of children with cancer are cured; however, over 85% of childhood cancers occur in developing countries where cure rates often do not exceed 35% (Barr, et al., 2006). As public health improves in developing countries and common childhood diseases such as infection, respiratory illness, and malnutrition become less important contributors to mortality, childhood cancer takes on increasing importance (Howard et al., 20007).

One of the key principles contributing to successful treatment of childhood cancers is the provision of care in pediatric cancer units by specialized professionals (Wagner & Antic, 1997; McGregor et al., 2007). Nurses are essential to the successful treatment of children with cancer and the provision of quality nursing care to pediatric oncology patients requires advanced knowledge and clinical skills (Hockenberry & Kline, 2006). Most hospitals in developed countries provide extensive pediatric oncology education and training to newly hired nurses and require nurses to complete a chemotherapy certification course before administering these drugs. In contrast, pediatric oncology education and training is generally not available for nurses in developing countries and is potentially one of the reasons for the disparity in survival rates (Wilimas et al., 2003). This major deficit of clinical practice is widely recognized. In most developing countries nurses are undereducated and simply not able to meet the demands of caring for children with cancer (Barr et al., 2006). A second critical problem in developing countries is the workload of the nurse with a patient to nurse ratio much higher than recommended for pediatric oncology nursing care (Day et al., 2008).

Conceptual Relationships

Staffing and Mortality

Several landmark studies have demonstrated that inadequate nurse staffing results in longer hospital stays, increased risk for complications, and an increase in mortality. A study investigating nurse-patient ratios on a given general unit found that the optimal workload for a nurse was 4 patients, and a workload of 8 patients versus 4 was associated

with a 31% increase in mortality (Aiken, Clarke, & Sloane, 2002). Another study found, after adjusting for patient and hospital characteristics, that each additional patient per nurse was associated with a 7% increase in the likelihood of dying within 30 days of admission and a 7% increase in the odds of death following complications (Aiken, Clarke, Sloane, Sochalski, & Silber, 2002). A study by Needleman, Buerhaus, Mattke, Stewart, and Zelevinsky (2002) demonstrated that higher nurse staffing levels resulted in reduced numbers of urinary tract infections, pneumonias, upper gastrointestinal bleeding, and shock in medical patients and lower rates of death following complications in major surgery patients.

Kane et al. (2007) conducted a systematic review and meta-analysis of research on the relationship between nurse staffing and patient outcomes. This review concluded that studies with different designs demonstrate associations between increased nurse staffing and lower odds of hospital related mortality and adverse patient events. The evidence consistently suggested that the odds of hospital-related mortality were 9-16% lower for each additional full time registered nurse per patient day. A very recent large-scale study conducted by Aiken, Clarke, Sloane, Lake, and Cheney (2008) concluded that surgical mortality rates were greater than 60% higher in poorly staffed hospitals with poor patient care environments than in hospitals with better care environments, the best nurse staffing levels, and the most highly educated nurses. Although most research to assess the association between nurse staffing and patient outcomes has been conducted in US hospitals, studies in Canada (Estabrooks et al., 2005) and England (Rafferty et al., 2007) have shown consistent results. To date, no studies have been done in developing countries.

Nursing Education and Mortality

Most hospitals in developed countries provide extensive pediatric oncology education and training to newly hired nurses and require nurses to complete a chemotherapy certification course before administering these drugs. In contrast, pediatric oncology education and training is generally not available for nurses in developing countries and is potentially one of the reasons for the disparity in survival rates (Wilimas et al., 2003). The assessment findings in Guatemala clearly documented the lack of pediatric oncology nursing education and skills training. This major deficit of clinical practice is widely recognized. According to Barr et al. (2006) in most developing countries nurses are undereducated and simply not able to meet the demands of caring for children with cancer. Expert pediatric oncology nursing care requires skills based on extensive knowledge of pediatric cancer. Pediatric oncology nurses play a major role in managing disease-related complications, coordinating care for central venous lines, and administering chemotherapy (Hockenberry & Kline, 2006).

Several recent large scale studies in the United States and Canada have suggested that the educational preparation of nursing staff contributes to patient outcomes such as mortality (Aiken et al., 2003; Elixhauser et al., 2003; Estabrooks et al., 2005). Aiken and colleagues (2003) demonstrated that in hospitals with higher proportions of nurses

educated at the baccalaureate level, surgical patients experienced lower mortality and failure-to-rescue rates. Estabrooks and colleagues (2005) also demonstrated that hospitals with a higher proportion of baccalaureate-prepared nurses were associated with lower rates of 30-day patient mortality.

In the U. S. and other developed countries hospital staff orientation and continuing education programs are well established and universally accepted as an important component of nursing thus studies to measure their impact are limited. However, there is strong evidence linking staff education to mortality from nosocomial infections in both developed and developing countries. Numerous studies in the U. S. have been published in support of staff education to reduce intravascular catheter-related infection rates. Eggimann et al. (2000), Coopersmith et al. (2002), and Warren et al. (2004) have reported studies showing education on catheter care and insertion reducing infection rates by 41 to 66%.

Rosenthal et al. (2006) researched the incidence of device-associated infection in ICU's of 8 developing countries. He concluded that health care associated infections are a serious and mostly unrecognized threat to patient safety in the developing world. Overall, health care associated infections and bacterial resistance are 3 to 5 times higher in developing countries than international standards and increase length of stay, costs, and mortality. A study conducted in Argentina demonstrated that implementation of process surveillance, education, and performance feedback increases compliance with hand hygiene and other infection-control interventions and significantly reduces the rates of central line associated blood stream infections, catheter associated urinary tract infections, and ventilator associated pneumonia device-associated infections (Rosenthal, 2008).

A study conducted in a public hospital in Mexico by Higuera et al. (2005) demonstrated that implementation of an infection control program which included education, process control, and performance feedback was associated with significant reductions in rates of intravascular device associated bloodstream infection and mortality. In Guatemala, after 3 months of infection control surveillance and an education program focused on respiratory care, the rate of nosocomial pneumonia decreased from 33% to 16% (Berg, Hershov, Ramirez, & Weinstein, 1995).

A literature search for publications on general staff education and impact on mortality in developing countries found one study done in Zambia which demonstrated a 6 month training course for nurse midwives was associated with a decrease in early neonatal mortality rates (Chomba et al., 2008). A very recent study evaluated the impact of training birth attendants in the World Health Organization Essential Newborn Care course and a modified version of the American Academy of Pediatrics Neonatal Resuscitation program on the rate of perinatal mortality in developing countries. Although birth attendants included traditional birth attendants, nurses, midwives, and physicians, the largest proportion of births was attended by traditional birth attendants. The study found no significant decrease in neonatal death from all causes in the first 7

days after birth or in the rate of perinatal death; however, a significant reduction in the rate of stillbirth was found (Carlo, et al., 2010).

Relationship of Staffing and Education to Abandonment

Abandonment of treatment (4 weeks of missing appointments during active treatment) is a critical problem in developing countries. Numerous studies have looked at causes of abandonment. A study by Metzger et al. (2003) systematically attempted to determine factors relating to abandonment and concluded that abandonment was associated with prolonged travel time to the treatment facility. In a study of acute lymphoblastic leukemia patients, Mostert et al. (2006) reported that 47% of the poor, but only 2% of the prosperous patients abandoned treatment. They concluded that poor patients received less individualized attention from staff and less parental education, which resulted in a lack of insight by parents regarding the need to continue therapy. A study by Bonilla et al. (2009) determined that within a setting where all treatment was provided at no cost to the family, only socioeconomic variables significantly predicted the risk of abandonment of therapy. They concluded that low economic status may be a proxy for poor understanding of either the seriousness of the condition or the potential curability of the cancer. A retinoblastoma program implemented in three Central American countries demonstrated a decrease in patient abandonment. The program focused on implementing early diagnosis measures, improving treatment protocols, establishing local provider networks, training local healthcare providers, supplying modern equipment, and improving communication. Also crucial to decreasing abandonment was the financial and social services help given to families by local nonprofit foundations (Wilimas et al, 2009).

A study in Indonesia concluded that reducing treatment abandonment of childhood acute lymphoblastic leukemia in developing countries requires not only financial and transportation support but also parental education, counseling and psychosocial support, improvement in quality of care, and adequate management of side effects (Sitaresmi, Mostert, Schook, Sutaryo, & Veeman, 2009). A systematic review of medical literature for evidence on causes of abandonment and interventions was conducted by Arora, Eden, and Pizer (2007). They concluded that abandonment is related to socio-economic and educational status of parents, travel time to treatment centers, and affordable and locally available treatment and that twinning between institutions has been shown to be effective in decreasing abandonment. Probably the most relevant study to this research proposal was conducted by Howard et al. (2004). This study measured the outcomes of a twinning program between Recife, Brazil and the International Outreach Program at St. Jude Children's Research Hospital. After implementation of a dedicated pediatric oncology unit, protocol-based therapy, specially trained nurses, and 24 hour on site physician coverage, the 5-year event free survival rate improved and the rate of abandonment of treatment decreased from 16% to 1.3%.

No specific studies have been done to determine the relationship between abandonment of treatment in developing countries and interventions only related to

nursing. However, a well educated nursing staff with more time to teach due to improved staffing could theoretically decrease the patient abandonment rate. This research proposal will be the first study to examine the effects of improved nurse staffing and education on abandonment of treatment.

CHAPTER 3. METHODOLOGY

The methodology chapter describes the study's design, internal and external validity, control and intervention site comparison, and instrumentation. It also includes a description of program implementation, fidelity, consideration of human subjects and statistical analysis.

Study Design

The purpose of the study was to evaluate the Guatemalan Nursing Program's (GNP) impact on staff, organizational, and clinical outcomes. Staff and organizational outcomes were evaluated using a before and after one group design often used in program evaluation. The clinical outcomes were evaluated using a control site comparison but no randomization and was therefore a quasi-experimental design.

Variables analyzed included staff variables of a) continuing education hours, b) chemotherapy competency, c) central venous line care competency, and d) pediatric oncology nursing education course completion, organizational variables of a) JCI standards, and b) patient to nurse ratio, and clinical variables of a) event free survival (EFS), and b) abandonment of treatment. The sample used to measure staff variables consisted of 49 professional nurses employed full time at the Guatemalan site and not in a management position. The sample used to measure event free survival and abandonment consisted of all patients entered in the Pediatric Oncology Networked Data Base (POND) diagnosed with cancer from January 1, 2004 to October 1, 2008. For analysis, the sample was further divided into two groups: pre program group and post program group.

The principal investigator traveled to the intervention site in July of 2009 to collect data to evaluate the staff and organizational outcomes. The education charts of all professional nurses who qualified for the study were reviewed and results documented on a data collection assessment form. The nursing quality assessment was used to evaluate the organizational outcomes. The same process used to conduct the initial nursing assessment completed in April of 2006 was used to conduct the post intervention assessment, and the same standards within the 6 designated JCI (Joint Commission International) domains were evaluated. The assessment was scheduled in advance with the partner site's leaders, and 4 full days were spent assessing the site. The assessment consisted of interviews with medical, administrative, and nursing leaders, and group interviews with staff nurses. Patient records, human resource documents, policies, and procedures were reviewed. Data for patient outcome variables were obtained using POND, which is used by all St. Jude partner sites including Guatemala and Honduras.

Internal and External Validity

Internal validity is the extent to which an inference can be made that the independent variable (the intervention) influenced the dependent variables (Polit & Beck, 2008). Some of the most critical threats to internal validity of this study included extraneous variables, fidelity, and maturation. The primary method used to mitigate threats to internal validity was the quasi-experimental design of the study. The experimental design is the gold standard in research and provides a level of confidence in interval validity that other designs cannot attain. The quasi-experimental design is the second strongest research design.

Using subjects that are homogeneous is an additional design method that was used to control for extraneous variables. According to Needleman and Buerhaus (2003) it is more likely that an association is observed between nurse staffing and mortality in subpopulations in which risk is more homogeneous. Comparisons of event free survival and abandonment were done on all cancer patients and also on a more homogeneous subgroup of patients with acute lymphoblastic leukemia. In the sample used to measure staff outcomes variation was controlled by including only full time professional nurses and excluding nurses who were in management positions and those who had worked in the unit for less than six months.

Program fidelity was a potential threat to internal validity. With both an experimental design and a quasi-experimental design, the fidelity of the intervention should be determined first. The intervention must be implemented as designed and well documented to determine a causal relationship with outcomes. This is especially challenging in a study that involves an intervention that occurred over a prolonged period of time, in this case 3 years. For this study, a process evaluation was done to determine if the education intervention was implemented as designed, specifically did the educator appropriately execute the responsibilities of the position.

Maturation was an additional threat to internal validity and refers to the processes that occur within subjects as a result of the passage of time rather than the intervention. For example, the nurses could gain knowledge over the course of the study due to experience and maturity. However, pediatric oncology skills are highly specialized and not likely to be acquired without formal instruction.

External validity is correlated to the extent the sample is representative of the population and the study setting and experimental arrangements are representative of other environments (Pedhazur & Schmelkin, 1991). The intervention site in Guatemala is the only treatment site for pediatric oncology patients and also the only employer of pediatric oncology nurses in the country, thus the study sample was very representative of the country of Guatemala. The broader questions include: Are pediatric oncology nurses in Guatemala similar to pediatric oncology nurses in other Latin American countries? Are pediatric oncology patients similar to pediatric oncology patients in other Latin American countries? Are the settings similar? Based on the strong similarities with the control site

in Honduras, the results could be generalized to this group. Generalization to other sites would be more difficult.

Control Site and Intervention Site Comparison

A control group (Honduras) was used to evaluate the performance of the intervention site (Guatemala) on the clinical variables of event free survival and abandonment. When using a control site, it is important to determine if the two sites are comparable.

The intervention site in Guatemala City, Guatemala was opened in 2000 with financial support from the country's Ministry of Health, a local non-governmental philanthropic foundation, and St. Jude. Guatemala is a country with an estimated population of 12.7 million. The primary language is Spanish, but 23 officially recognized Amerindian languages are also spoken. The literacy rate is about 70% with 56% of the population living below the poverty level. The infant mortality rate is 30 deaths per 1000 live births and the life expectancy at birth is 70 years (World Factbook, 2009). The pediatric oncology unit, the site affiliated with St. Jude, functions independently within a much larger public hospital system. Approximately 1000 patients are seen annually, and the unit averages a 95 to 100% occupancy rate. For all cancer patients diagnosed between January 1, 2004 and December 31, 2006, the 1- year event free survival (EFS) estimate was 70.98 ± 1.91 .

The control site in Tegucigalpa, Honduras was also opened in 2000 with financial support provided by the country's Ministry of Health, a local non-governmental philanthropic foundation, and St. Jude. The Spanish language is the predominant language; however, indigenous Amerindian languages in several dialects and Garifuna are also spoken. Both countries have similar demographics. Honduras has an estimated population of 8 million with approximately 51% of the population living below the poverty level. The life expectancy at birth is 69 years and the infant mortality rate is 26 deaths per live births (World Factbook, 2009). The pediatric oncology unit is located within the Materno-Infantil (mother and child) section of Hospital Escuela, a tertiary general referral hospital with 2000 beds. Approximately 800 patients are seen annually with a 100% occupancy rate. For all cancer patients diagnosed between January 1, 2004 and December 31, 2006, the 1-year EFS estimate was 76.77 ± 2.12 .

Both sites have similar nursing organizational structure and similar undergraduate (pre- licensure) educational preparation. The organizational structure includes a head nurse, assistant head nurses for specific units, and professional and technical staff nurses. The educational preparation of professional nurses is 3 years of training in a public university or independent nursing school. In 2007, the quality of nursing care at the control site was assessed; the same JCI standards used to assess Guatemala were used. The assessment results were similar in that both sites only met a minimal number of standards. Because of administrative issues, the nursing program has not been implemented in Honduras.

Both sites have implemented similar efforts to prevent abandonment. The site in Honduras has 2 psychologists who counsel families and 3 satellite clinics to help families who live long distances from the hospital. Guatemala has 2 full time psychologists and one part time psychologist. Guatemala does not have satellite clinics but provides transportation assistance. Both sites provide housing to families whose child is receiving treatment.

Interventions in clinical settings provide a challenge because of the lack of control of the environment. For this study it was important to determine if critical changes in clinical care occurred at either the control or intervention site (other than the nursing intervention) during the 3 year assessment period. In addition, it was important to determine if there were major changes in program organization and staffing involving critical leadership positions. Based on interviews with leaders at both sites, during the past 3 years treatment protocols had not been changed. Also during this time period, the medical director, head nurse, and lead psychologist positions had not changed at either site. An infection control program was implemented at both sites in July of 2007, which involved hiring a part time physician and a full time infection control nurse. The site in Guatemala was undergoing construction but did not move to the new facilities until after study completion. In addition, a review of POND data determined that patient demographics had remained stable. The most inherent difference between sites was that Guatemala functioned mostly independently within a much larger public hospital system, and Honduras was more dependent on the public hospital system for support.

In summary, the intervention site and the control site shared similar demographics, financial support, nursing structure, abandonment prevention strategies, and patient population. Although for patients diagnosed between January 1, 2004 and December 31, 2006, Honduras had a slightly higher 1-year EFS estimate than Guatemala. In addition, no critical changes in clinical care occurred at either the control or intervention site, and there were no major changes in program organization and staffing involving critical leadership positions.

Instrumentation

This section will discuss the validity and reliability of the instruments used to measure the study's outcomes, and includes JCI standards, chemotherapy evaluation test, central venous line care evaluation test, pediatric oncology evaluation test, and the POND data base.

Joint Commission International (JCI) Standards

In Guatemala, nursing quality was assessed using standards from six JCI quality domains. The JCI standards have been tested for validity, or the degree an instrument measures what it is intended to measure, in this case, quality of care. Content validity is the degree an instrument has an appropriate sample of items for the construct being

measured. Validity of an instrument is more difficult to establish than reliability, and is necessarily based on judgment. There are no absolutely objective methods of determining content validity of an instrument (Lynn, 1986; Polit & Beck, 2008). The JCI standards were developed by an international task force consisting of members from Latin America and the Caribbean, Asia and the Pacific Rim, the Middle East, Central and Eastern Europe, Western Europe, and Africa, and have been validated through quality and safety studies by public agencies and ministries of health outside the U.S. In addition, the standards have recently been evaluated by JCI Regional Advisory Councils and by persons from around the world via an Internet based field review (Joint Commission International, 2007). An instrument's reliability is the consistency it measures the target attribute, in this case quality of care. Reliability is improved by the more items that measure a particular concept. For example, multiple standards are used to assess each of the JCI's six domains. According to Polit and Beck, the most effective method of improving reliability is to train the observer. The principal investigator's initial training included working with St. Jude's Standards and Practice Coordinator, a nurse experienced in conducting Joint Commission assessments. Although the principal investigator's experience began in the United States, she has conducted numerous assessments at St. Jude's partner sites throughout Latin America. However, the reliability of an instrument is not a property of the instrument itself. When selecting an instrument it is vital to know the characteristics of the group for whom it was created. JCI standards were developed for use within a specific population of health care organizations, and included public hospitals in developing countries. The standards take into account that hospitals in many developing countries do not yet function at the level of U.S. hospital standards; therefore, they are less stringent in evaluation criteria (Marshall et al., 2006). The standards have been adapted for the international community and are designed to be culturally applicable and compliant with laws and regulations outside the U.S. (Timmons, 2007). A set of standards this broad in nature cannot account for a country's unique characteristics; however, there is evidence that many quality concerns are universal. Aiken, Clarke, and Sloane (2002) noted that countries tend to believe problems with quality of care and nurse staffing are a result of unique circumstances. Yet, data from their study suggested that contrary to popular opinion, many hospital problems know no country boundaries.

The JCI standards have both strengths and weaknesses. They are universally recognized as the gold standard for international accreditation and the process of accreditation has gained international acceptance as an effective quality evaluation and management tool. These facts captured the attention of partner site leaders who possessed the authority and financial access to support the program. Also the assessment findings provided the baseline from which nursing needs were determined and provided the organizational framework for program development. The JCI standards are currently the best option available to assess quality of care in an international health care setting. The Association of Pediatric Hematology Oncology Nursing has developed a set of nursing standards; however, the standards are not precisely defined and were not designed to be used for the purpose of assessment (Nelson et al., 2007). The JCI standards are not specific for nursing. The standards used for the partner site assessment were selected based on their relevance to nursing; the selection process was informal and involved a

small group of pediatric oncology nurses from St. Jude. All standards are given equivalent value and are rated as met, not met, or partially met.

Evaluation Tests

Evaluation tests were used to measure competency in chemotherapy and central venous line care and successful completion of the pediatric oncology nursing education course for newly hired nurses. Competency in chemotherapy is defined as documented chemotherapy course completion in the nurse's education record, including course title, date and hours of course, presenter, and evaluation score. A course evaluation score of $\geq 70\%$ is required for competency. Competency in central venous line care is defined as documented central venous line care course completion in the nurse's education record, including course title, date, hours of course, presenter, and evaluation score. A course evaluation score of $\geq 70\%$ is required for competency. The pediatric oncology nursing education course for newly hired nurses is defined as 5 consecutive days of documented theoretical presentations and 5 consecutive days of documented clinical experience with a preceptor. An evaluation test score of $\geq 70\%$ is required for successful completion of the course.

The evaluation tests were developed by the nurse educator in Guatemala and the questions were based on the content taught. Content validity was assessed by nurse experts from the Latin American Center for Pediatric Oncology Nursing Education. Three nurses reviewed each question for relevance and clarity. The reviewers had access to the course content for reference. Revisions to several questions were made based on the review. A limitation to this study was the fact that the instruments were not rigorously assessed for content validity, and reliability testing was not done. However, knowledge assessment instruments developed by a local educator who recognized the baseline knowledge level of the staff were preferred to standardized tests, which had not been tested in this population or culture.

POND Data Base

The event free survival (EFS) rate and cumulative incidence of abandonment were determined using the International Outreach Program's online Pediatric Oncology Networked Data Base (POND), which is used by all St. Jude's partner sites, including Guatemala and Honduras. A recent study of data accuracy and completeness showed that the data were 99% accurate (except for cause of death, which was usually not well documented in the medical records) and 97% to 99% complete (Ayoub, et al., 2006). Event free survival (EFS) distributions were estimated by the method of Kaplan and Meier (1958) and were compared with log-rank test. Kaplan and Meier calculation is the most widely used method to estimate survival characteristics and is almost always used in pediatric oncology to estimate survival. Abandonment within the first year was estimated using CIN (Cumulative Incidence) and compared using Gray's test (Gray, 1988). When competing risks are present, the appropriate estimate of the failure probabilities is the

cumulative incidence. A competing risk is defined as an event whose occurrence alters the probability of occurrence of the main event under examination, in this study death is a competing event with the main event of abandonment. A summary of measurements used in this study is included in **Table 3.1**.

Implementation and Fidelity of the Guatemalan Nursing Program

Fidelity is how well a program is operationalized—specifically, was the program implemented as designed. This section describes the overall implementation and thus fidelity of the Guatemalan Nursing Program (GNP) and includes: implementation of the education intervention, the process evaluation of the education intervention, and the implementation of the staffing intervention.

Implementation of Education Intervention

Development of the Nurse Educator Position. Developing the nurse educator position involved working within the departments of nursing, administration, human resources, and medicine, and the philanthropic foundation. A nurse dedicated to education and not responsible for providing direct patient care was a new concept for the hospital in Guatemala, and establishing this position presented many challenges. The first step involved financial negotiations with the philanthropic foundation. An agreement was reached that the foundation would provide funding for benefits, and the IOP would provide funding for the salary. The second step involved working with human resources to develop a job description and then meeting with nursing, medical, and administrative leaders to review and finalize the job description. After several meetings the job responsibilities and job requirements were agreed upon. The nurse educator's primary responsibilities included: implementing a pediatric oncology education course for newly hired nurses, providing continuing education, teaching courses in chemotherapy administration and central venous line care skills, improving quality standards relevant to nursing (in collaboration with IOP Nursing Director), and serving as the primary nursing liaison with IOP. Initially the administrative and medical directors were insistent that a physician be hired for the position, reflecting their lack of confidence in a nurse's ability to perform the responsibilities. The third step involved candidate selection. The process of candidate selection involved working with nursing management and human resources; the challenge was to ensure the selection process was perceived as fair by the nursing staff. The position was advertised within the partner site and in the local newspaper. Interviews were conducted by hospital leaders and the IOP nursing director. A full-time educator was hired in January 2007. The nurse assuming the position had worked at the site in the intensive care unit and was well respected by the nursing and medical staff.

Nurse Educator Preparation and Support. In March of 2008, the nurse educator from Guatemala successfully completed the Comprehensive Educator Course at the Latin American Center for Pediatric Oncology Nursing Education in Santiago, Chile. The

Table 3.1 Measurements for Staff, Organizational, and Clinical Outcomes

Outcomes Measurement	
Staff Outcomes	
Pediatric oncology education course for newly hired nurses	Pediatric oncology evaluation test
Central venous line care competency	Central venous line care evaluation test
Chemotherapy competency	Chemotherapy evaluation test
Continuing education hours	Attendance at education class with documentation in education record
Organizational Outcomes	
Nursing quality standards	Joint Commission International Standards
Patient to nurse ratio	Staff interviews, direct observation, human resource records
Clinical Outcomes	
Event free survival	Kaplan Meier Method compared using Log-rank Test
Abandonment	Cumulative incidence estimate compared using Gray's Test

Center's development and role in providing education, resources, and support to pediatric oncology nurse educators in Latin America is described in this section.

A full-time nurse educator dedicated to a specific hospital unit was a new concept in most developing countries, where a large public hospital typically has only one educator (Day et al., 2008). Because of the novelty of the position, there were no local role models to mentor the educators. Although the educators were carefully selected, they had limited teaching experience and had never received formal pediatric oncology training. Clearly, the educators needed help to succeed in their pioneering role. To meet this need, the Latin American Center for Pediatric Oncology Nursing Education was created at Calvo Mackenna Hospital in Santiago, Chile.

In 2007, the IOP nursing director and St. Jude leaders proposed to Calvo Mackenna Hospital that the St. Jude IOP Nursing Division and the Calvo Mackenna Nursing Division collaborate to create a Latin American Center for Pediatric Oncology Nursing Education at Calvo Mackenna. Calvo Mackenna was selected as the Center site for several reasons: the hospital valued nursing, nursing and medical leaders were supportive of the idea and amenable to collaboration with St. Jude, the nursing division was well organized and worked well with other disciplines, and there was a dedicated pediatric oncology nursing staff that valued the role of education. Another significant factor was the mutual respect between nurses and physicians in the pediatric oncology unit, where nurses participated in daily rounds and patient conferences and actively communicated with the physicians and other team members. Initially, the IOP nursing director and the IOP medical director of the pediatric oncology partner program at Calvo Mackenna met with nursing, medical, and administrative leaders of both hospitals and with the Chilean Ministry of Health to discuss the need for the Center and the collaboration and support required to ensure success. After much negotiation, leaders at St. Jude and Calvo Mackenna agreed to pursue the creation of the Latin American Center for Pediatric Oncology Nursing Education as a joint venture. St. Jude and Calvo Mackenna shared a similar vision for the Center and appreciated the positive impact it could have on pediatric oncology nursing throughout Latin America. The next step was to hire an on-site coordinator to work with the IOP nursing director to develop and direct the Center. An experienced bilingual pediatric oncology nurse with strong leadership and teaching skills was hired in late 2007. The Center's coordinator works closely with Calvo Mackenna's pediatric oncology nurse educator, who was also hired in 2007 and is supported by the IOP nursing program.

A mission statement and goals were developed by the IOP nursing director in collaboration with nursing leaders at Calvo Mackenna. The mission of the Center (to promote excellence in pediatric oncology nursing education in Latin America) is consistent with the mission of the IOP nursing program, which is to promote the highest quality of nursing care for patients and families at the IOP partner sites. A skilled educator can significantly improve nurses' ability to provide quality care. The Center's goals were to provide nurse educators with the education and skills needed to succeed in their role; to provide centrally developed nursing educational resources; and to provide ongoing support, education, and mentoring to nurse educators.

Goal 1 was to provide the nurse educators with education and skills needed to succeed in their role. A 4-week comprehensive educator course was developed to meet this goal. The Center's nurse coordinator and Calvo Mackenna's pediatric oncology nurse educator developed the course and served as the lead instructors. The course's structure included four components: pediatric oncology lectures, instruction in the use of educational resources and teaching methodology, a self-directed project, and direct observation of patient care. The Guatemalan nurse educator and other nurse educators from Latin America traveled to Chile to attend the educator course. An offsite course was an important benefit for adult learners because it eliminated many of the demands on their time and allowed them to focus more completely on the course.

Day 1 of the course was designed to focus on the nurse educators' perspectives and experience relevant to the course content. The instructors discussed the relevance of the content and how it would be useful in their new role as an educator. Most important, the instructors acknowledged the wealth of experience the educators brought to the course and treated the nurses as peers in experience and knowledge. The first component of the educator course included pediatric oncology lectures, an appropriate educational method for presenting science based content. The goal was to provide lectures which encouraged the educators' participation and were not completely instructor focused. After each lecture, ample time was allowed for discussion and questions. The second component of the course included instruction in the use of educational resources developed by the Center and teaching methodology. The third component of the course included a self-directed learning project. Each nurse educator was asked to identify a self-directed learning project to be completed during the educator course. For example, one educator selected patient education as the focus of her project. She studied patient education principles and created a central venous line education booklet for parents. The fourth component included direct observation of patient care. Most of the participants in the nurse educator courses come from hospitals with very limited resources. Observation of quality nursing care provided within a well organized system was a crucial part of their learning experience. The nurse educators spent time in both the inpatient and outpatient units, where they observed nursing care and participated in multidisciplinary rounds.

In 2009, teaching methods based on Malcolm Knowles' adult education theory were incorporated into the educator course. This theory was selected because the educators had received no formal education specific to pediatric oncology and had limited teaching experience, yet they were experienced nurses with a wealth of knowledge (Knowles, 1970). For the nurses who attended the course prior to 2009, presentations on adult learning principles were provided via Horizon Live web meetings. Because the educator course has had only a small number of students at any one time and has a wealth of resources, adult learning principles were easily integrated. However, the nurse educators are responsible for educating a large number of staff nurses and many adult education principles, such as individual learning objectives and independent learning projects, are impractical. Nevertheless, many of the principles have been incorporated and include encouragement of a collaborative relationship, use of a democratic learning process, and nurses' discussion of their relevant experiences.

Further, because adult learners often fear failure, the educator tries to create a relaxed and safe environment. Most importantly, the educator shows respect to the nurses and encourages their feedback.

Goal 2 was to provide centrally developed nursing education resources. Few pediatric oncology educational resources are available in Spanish. Each nurse educator did not need to develop his/her own materials for several reasons. First, the educators lacked the time, resources, and experience to develop quality educational materials. Second, centrally developed resources would promote the standardization of nursing education and policy development. It was agreed that each site would adapt the materials to meet its staff's needs, while the overall concepts taught would remain the same. To date, curriculum resources developed for universal use in Latin American partner sites include a chemotherapy skills check list, a chemotherapy instruction manual for nurses, and a central venous line care education video. To establish content validity, all materials were reviewed by a group of experienced pediatric oncology nurses, physicians, and pharmacists from Santiago, Chile. All educational resources, including a compact disk containing pediatric oncology lectures, were given to each educator to take to their facility.

Goal 3 was to provide ongoing support, education, and mentoring to nurse educators. The subspecialty educator position is a unique role in developing countries, and ongoing professional support is crucial to successful establishment of the position. Several initiatives have been implemented to provide this support. Nurse educators attend bimonthly Horizon Live web meetings (directed by the Center's coordinator and the IOP nursing director) that provide ongoing education, support, and mentoring. Meetings include presentations on relevant topics and allow ample time for discussion of issues and challenges. Recent topics presented included: adult education theory, teaching skills, palliative care, pain management, and chemotherapy administration. The IOP nursing director also conducts a monthly telephone conference with each educator to provide individual support and identify any administrative issues that need attention. The IOP nursing director works closely with the medical and administrative directors at each partner site to ensure that the educators receive institutional support. For example, administrative intervention by the IOP nursing director was needed at all sites to ensure that nurses were permitted to attend classes regularly, and at many sites negotiation has been necessary to secure a location for the classes. Nurse educators attend the annual meeting of the Pediatric Hematology/Oncology Association of Central America, where they share their work with the group. The Center's coordinator also presents newly developed educational resources and provides updates on pediatric oncology nursing education at this meeting.

The Center was founded in 2007 with the development of a mission statement and goals, the hiring of a coordinator, and administrative planning and organization. The Center's coordinator began work on goals 1 and 2 in November 2007. By March 2008, the educator course was ready for implementation and by 2009 educational resources had been developed. In 2008, the first 4-week educator course was held in Santiago, Chile and was attended by three nurse educators from Guatemala City, Guatemala; San

Salvador, El Salvador; and Tijuana, Mexico. A second course in the fall of 2009 was attended by two nurse educators from Bogota, Colombia. Plans to implement a pediatric oncology nursing education program in San Jose, Costa Rica; Culiacán, Mexico; and Tegucigalpa, Honduras, are under way, and educators from these sites are expected to attend the course in 2010. Although the primary purpose of the Center is to train and support nurse educators, future plans include support for management and leadership roles as well. Therefore, leadership presentations will be incorporated into the course curriculum and specific resources will be developed to support nurses in management roles.

The initial phases of program development and implementation have been completed; therefore, the next phase will include program evaluation. A process evaluation will be conducted to determine whether the program has been implemented as designed, and outcome evaluations will assess the impact of the program on the nurse educators and the staff they educate. Current methods of evaluation include pre- and post-course evaluation tests and a course evaluation survey. These outcome data are being accrued, and the development of additional methods of evaluation, including measurement of the educator's impact on staff and clinical outcomes, is planned. The curriculum and knowledge assessment measures have been improved on the basis of verbal feedback and course evaluation surveys. Educational resources will be continually updated and revised to reflect the most recent published evidence, and expert peer review will be ongoing.

Process Evaluation

A process evaluation was done to determine if the educator appropriately executed the responsibilities of the position. The nurse educator's primary responsibilities, as designated in the educator job description, included: implementing a pediatric oncology education program for newly hired nurses, providing continuing education, teaching classes in chemotherapy and central line care, improving quality standards relevant to nursing (in collaboration with IOP nursing director), and serving as the primary nursing liaison with the IOP nursing director.

Process evaluation, which should occur in the early stages of a program, had been an important component of the Guatemalan Nursing Program since inception. A monthly report was submitted by the nurse educator to the IOP nursing director that included specific activities performed as related to the responsibilities designated in the educator's job description. A standard reporting format was used to ensure activities were consistently documented. Reports were reviewed by the IOP nursing director and the results discussed during monthly phone conferences.

For this study, a specific process evaluation was done and included a description of the educational content and the number of education activities provided by the nurse educator. The focus of this evaluation was on what the educator provided; staff outcomes related to education were evaluated separately. The specific activities evaluated included:

pediatric oncology nursing education course for newly hired nurses, chemotherapy course, central venous line care course, and continuing education classes provided during year 2008. These activities occurred in the implementation domain of the Guatemalan Nursing Program as depicted in the program logic model.

Educational Content. The pediatric oncology education course was designed to teach new nurses the basic clinical and theoretical aspects of pediatric oncology nursing care. Its theoretical component included presentations on common pediatric cancers; prevention, early detection, and treatment of complications; pain management; prevention of infections; and oncologic emergencies. Its clinical component included hands-on instruction in chemotherapy administration. The chemotherapy course offered a more advanced theoretical understanding of chemotherapy agents. The course included 4 lectures focused on the biological basis of cancer, classification of chemotherapy agents, and the nursing implications of chemotherapy administration, including safe handling and management of side effects. The central venous line course included three presentations on the basics of central venous lines and on recognizing and preventing complications. An accompanying video demonstrated the proper nursing care of external and implantable long-term central lines.

Education Activities. The nurse educator provided all 25 of the professional nurses hired after program implementation (January 1, 2007) a pediatric oncology nursing education course. From January 1, 2007, to October 1, 2009, the nurse educator provided a chemotherapy administration course to 45 of the 49 professional nurses, and during the same time period, the nurse educator provided a central venous line care course to 29 of the 49 professional nurses. During 2008, the nurse educator provided 134.5 hours of continuing education. Year 2008 was used to ensure a full 12 months evaluation period. Continuing education classes for 2008, including class subject, class hours, times presented, and hours of education per subject, is presented in **Table 3.2**

Implementation of Staffing Intervention

The process for improving the patient to nurse ratio in Guatemala consisted of documenting and justifying the need, meeting with medical and administrative leaders to create new positions, and negotiating with the foundation leaders to secure funding. The 2006 JCI assessment determined that a staffing plan to confirm patient to nurse ratios was not done. There was also no evidence that assignments were based on scope and frequency of care required and skill level of the nurse. According to staff interviews and direct observation in the intermediate, isolation, and general care units, the patient to nurse ratio was from 6 to 8 patients per nurse. All pediatric oncology patients are considered high acuity because of the scope and frequency of care required. A patient to nurse ratio of 4 to 1 is recommended for general units patient to nurse ratio of 2 to 1 is recommended for critical care areas.

One of the obstacles to improving staffing was the lack of value and respect for nursing expressed by hospital leaders. There was strong evidence from the initial

Table 3.2 2008 Continuing Education Classes

Class Subject	Class Hours	Times Presented	Hours per Subject
Chemotherapy administration	4	3	12
Care of central venous lines	4.5	2	9
Care of peripheral lines	1.5	1	1.5
Nutritional needs of oncology patients	1	1	1
CPR	2	4	8
Hand hygiene & prevention of infections	3	3	9
Microbiology basics	1	1	1
Review of acute lymphoblastic leukemia	3	3	9
Review of acute myelogenous leukemia	1	1	1
Treatment of osteosarcoma	2	1	2
Treatment of Ewing sarcoma	1	1	1
Review of nursing process	2	4	8
Cancer genetics	3	1	3
Management of treatment side effects	2.5	2	5
Recognizing signs of septic shock	2	5	10
Anatomy & physiology of circulatory system	4	1	4
Review of lab values	1.5	1	1.5
Management of critical patients	4	1	4
Advancing nursing care by better documentation	1	1	1
Safe patient transport	1	1	2
Treatment of fever and neutropenia	2	2	4
Nursing responsibilities for blood administration	2	4	8
Overview of childhood cancer	4	1	4
Oncologic emergencies	4	2	8
Safe handling of hazardous waste	3	1	3
Fluid balance and electrolytes	3	1	3
Pain management	2	1	2
Dosage calculation	2	2	4
Palliative care	2	1	2
Accident prevention	1	1	1
Protocol for administering antibiotics	1	1	1
Bioethics	1.5	1	1.5
Total classes and total education hours 56			134.5

assessment to support this conclusion and included: no support for nursing education, minimal communication with nursing staff, the nursing director managed nursing and housekeeping, and a very high patient to nurse ratio. The value of nursing needed to be advanced to convince leaders that new positions should be created. Presentations on the “Value of Nursing” were provided to leaders from medicine, administration, and the foundation. (Financial support for the pediatric oncology unit is provided by a local non-governmental philanthropic foundation dedicated to helping children with cancer.) The presentations were evidence based and included statistics from research done by Aiken, Clarke, Sloane, Sochalski, & Silber (2002) and Needleman et al. (2002). The well documented research provided the evidence needed to justify the creation of new nursing positions.

Negotiations with medical and administrative leaders resulted in an agreement that improved staffing would be a priority goal for years 2007 and 2008. The foundation agreed to support the goal and provide financial support for new nursing positions. Ten new nursing positions were created in 2007, and 14 were created in 2008. Candidates were interviewed by the head nurse and the nurse educator.

Consideration of Human Subjects and Statistical Analysis

The study received approval from St. Jude Children’s Research Hospital Institutional Review Board, the University of Tennessee Health Science Center Institutional Review Board, and the University of Guatemala Institutional Review Board. The study was granted expedited review status on October 19, 2009. All IRB guidelines were maintained. The St. Jude internal review board approval letter is included in Appendix A, and the University of Guatemala internal review board letter is included in Appendix B.

One-sample t-tests, exact Wilcoxon Signed-Rank tests, and exact Wilcoxon Rank Sum tests were conducted to analyze staff outcomes. Statistics were only applied to population groups with more than 10 staff nurses and 0.05 was the nominal significance level.

Event free survival (EFS) distributions according to different subgroups (Guatemala site versus Honduras site; patients diagnosed between January 1, 2004 and December 31, 2006 versus patients diagnosed between January 1, 2007 and October 1, 2008, respectively) were estimated by the method of Kaplan and Meier (1958), and were compared with log-rank test (Mantel, 1966). Kaplan and Meier calculation is the most widely used method to estimate survival characteristics and is almost always used in pediatric oncology to estimate survival.

Cumulative incidence (CIN) of abandonment within the first year was estimated as described by Kalbfleisch and Prentice (1986) and compared using Gray’s test (Gray, 1988). CIN of abandonment within the first year was defined as the time from date of diagnosis to abandonment within the first year, with death within the first year as competing event for abandonment. When competing risks are present, the appropriate

estimate of the failure probabilities is the cumulative incidence. A competing risk is defined as an event whose occurrence alters the probability of occurrence of the main event under examination, in this study death is a competing event with the main event of abandonment. When the aim is to estimate the failure probabilities, censoring is inappropriate because after a competing event has occurred failure from the cause of interest is no longer possible (Coviello & Boggess, 2004).

Chi-square test and Monte Carlo approximation (10,000 permutations, seed=3232010) of Wilcoxon rank sum tests were conducted to compare the differences in ages at diagnosis and patients' diagnosed cancer types between two sites (Guatemala site versus Honduras site); 0.05 was the nominal significance level. SAS version 9.2 (SAS Institute, Cary, NC) and StatXact (Cytel Corporation, Cambridge, MA) Windows version 8 were used for statistical analysis.

CHAPTER 4. RESULTS

The purpose of this study was to evaluate the Guatemala Nursing Program's (GNP) fidelity and impact on staff, organizational, and clinical outcomes. The results are organized and presented according to the study's specific aims in three sections: staff outcomes, organizational outcomes, and clinical outcomes.

Staff Outcomes

The sample consisted of 49 full time professional staff nurses. Staff nurse was defined as a full time professional nurse (working ≥ 30 hours per week) who had worked for a minimum of six months at St. Jude's partner site at the National Unit of Pediatric Oncology in Guatemala City, Guatemala and was not in a management position. Professional nurse was defined as a graduate from a school of nursing (diploma or university degree) as documented by the hospital's department of human resources. Forty-nine nurses met the defining criteria and all were included in the study. Their mean length of employment at the partner site was 3.5 years (range 0.5 to 9.6). The sample was predominately female (94%), and 48 (98%) had a nursing diploma, as opposed to a university degree. Twenty-four nurses (51%) were hired pre GNP implementation (before January 1, 2007), and 25 (49%) were hired post program implementation (on or after January 1, 2007). Age was not included in the demographics for identity reasons. Demographic characteristics of the staff sample are reported in **Table 4.1**.

The GNP's impact on staff outcomes was evaluated by comparing the percentage of nurses receiving education pre program implementation (before January 01, 2007) to the percentage receiving education post program implementation (on or after January 01, 2007). However, it should be noted that no documentation of staff education occurring prior to January 01, 2007 existed, resulting in pre program percentages of zero. In addition evaluation scores and continuing education hours were compared to desired outcomes or benchmark values.

Staff Specific Aim 1 compared the percentage of nurses hired post program implementation that successfully completed a pediatric oncology education course for newly hired nurses to an expectation of 100% completion rate. The pediatric oncology

Table 4.1 **Characteristics of Staff Sample (N = 49)**

Characteristics Total	Sample
Employment in years, mean (range)	3.5 (0.5-9.6)
Female, % (N)	94% (46)
Diploma	98% (48)
Hired pre GNP	49% (24)
Hired post GNP	51% (25)

education course for newly hired nurses was defined as 5 consecutive days of documented theoretical presentations and 5 consecutive days of documented clinical experience with a preceptor. An evaluation test score of $\geq 70\%$ was required for successful completion of the course. Of the 25 nurses hired post program implementation, all 25 completed the program. The mean evaluation score was 86.14 ± 7.43 (range 70-97%).

Staff Specific Aim 2 compared the percentage of nurses competent in central venous line care to pre program percentages. Competency in central venous line care was defined as a documented central venous line care course completion in the nurse's education record. Documentation included course title, date, hours of course, presenter, and course evaluation score. A course evaluation score of $\geq 70\%$ was required for competency. No nurses completed a central venous line care course pre program implementation. Post program implementation, twenty-eight nurses (57%) participated in the course and 22 (45%) successfully completed the course. Of the 28 participants, the mean evaluation score was 77.93 ± 14.73 (range 46-98%).

Specific Aim 3 compared the percentage of nurses competent in chemotherapy administration to pre program percentages. Chemotherapy competency is defined as a documented chemotherapy administration course completion in the nurse's education record. Documentation included course title, date, hours of course, presenter, and course evaluation score. An evaluation score of $\geq 70\%$ was required for competency. No nurses completed a chemotherapy administration course pre program implementation. Post program implementation, forty-two nurses (86%) participated in the course, and 39 (80%) successfully completed the course. Of the 42 participants, the mean evaluation score was 86.64 ± 9.74 (range 62-100%). **Table 4.2** summarizes staff education participation, completion, and evaluation scores by date of hire (pre versus post GNP).

Specific Aim 4 compared the mean annual hours of continuing education for year 2008 to the annual hours (10) of continuing education required for APHON certification. Continuing education hours was defined as documented attendance at an educational class. Education was documented in the nurse's education record and included title of class, hours of class, and presenter. A one-tailed one sample t-test was conducted to compare the mean annual hours of continuing education for year 2008 to the 10 annual hours of continuing education required for APHON certification. To ensure a full 12 month evaluation period, only nurses hired on or before January 1, 2008 were included. The mean annual hours of continuing education for 2008 (21.21 ± 8.04) was statistically significantly greater ($p < 0.0001$) than the 10 hours required for APHON certification.

Organizational Outcomes

Organizational Specific Aim 1 compared the percentage of JCI nursing quality standards met pre GNP implementation to post program percentages. The nursing quality assessment provided the data to evaluate the JCI standards. The same process used to

**Table 4.2 Staff Education Participation, Completion, and Evaluation Scores
by Date of Hire (Pre versus Post GNP)**

Professional Education	All Nurses (N = 49)	Nurses Hired Pre-GNP (n = 24)	Nurses Hired Post-GNP (n = 25)
Pediatric Oncology Program ^a			
Participated			25
Completed			25
Post evaluation score ^b			86.2 (70-97)
Central Line Care			
Participated	28 (57%)	7	21
Completed	22 (45%)	6	16
Post evaluation score	77.9 (46-98)	76.9 (60-90)	78.3 (46-98)
Chemotherapy Administration			
Participated	42 (86%)	18	24
Completed	39 (80%)	17	22
Post evaluation score	86.6 (62-100)	86 (62-100)	87.1 (64-100)

^a Nurses hired post program only

^b Mean and range

conduct the initial nursing assessment done in 2006 was used to conduct the 2009 post intervention assessment, and the same 20 standards within the 6 designated JCI domains were evaluated.

In 2006, of the 20 standards measured, only 1 (5%) standard was met, 2 (10%) were partially met, and 17 (85%) were not met. In 2009, the same 20 standards were measured, and 16 (80%) were met, 1(5%) was partially met, and 3 (15%) were not met. **Table 4.3** includes the 2006 and 2009 findings of the 20 JCI nursing quality standards evaluated.

Standard results were reported as met, partially met, or not met as follows:

1. Access to Care and Continuity of Care

Standard: The organization designs and carries out processes to provide continuity of patient care services in the organization and coordination among health professionals.

2006 Findings: The patient record is available on the unit for all healthcare providers to access. A nursing shift to shift report and unit to unit report is completed. A Kardex is used to help communicate patient care and treatment information to the nursing staff. There is a process in place to report to nursing staff on other units when a patient is transferred. There are no regular patient rounds or interdisciplinary meetings that include nurses. (Standard partially met.)

2009 Findings: The patient record is assessable for all providers. There is a separate nurse's chart that was very well organized and was easily located on the patient's door. The nurse's chart includes a standard assessment form that is detailed and organized. The nurse coordinator or the nurse manager of the unit makes rounds every morning with the physicians and documents appropriate notes related to the patient's care in the Kardex and the nursing chart. The morning rounds often include other disciplines such as pharmacy and psychology. (Standard met.)

Table 4.3 Comparison of 2006 versus 2009 JCI Nursing Quality Standards (N = 20)

JCI Standards	2006	2009
Met, % (N)	5% (1)	80% (16)
Partially met	10% (2)	5% (1)
Not met	85% (17)	15% (3)

2. Assessment of Patients

Standard: All patients cared for by the organization have their health care needs identified through an established assessment process.

2006 Findings: The policy of the institution regarding nursing assessments was unclear. There was no evidence that the nursing staff was conducting an initial nursing admission assessment. The staff described the process for reassessment as being required once each shift; however, chart review did not confirm this. There were several occasions when a nursing reassessment each shift was not recorded in the record, although there was a nursing flow sheet for this. (Standard not met.)

2009 Findings: The nursing policy states that all patients receive an initial assessment and are reassessed at the beginning of every shift. All assessments are documented on the recently developed comprehensive nursing assessment form which includes designated space for charting vital signs, review of systems, pain assessment, psychosocial evaluation, medications, procedures, intake and output, and nursing plan of care. A patient Kardex is also used that contains diagnosis, treatment plan, medications, and nursing plan of care. The Kardex used in 2006 included information written on a blank card. The Kardex used now is a standardized form that provides an organized method to summarize patient data. (Standard met.)

Standard: Each patient's initial assessment includes an evaluation of physical, psychological, social, and economic factors, including a physical examination and history.

2006 Findings: There was no documented initial nursing assessment; therefore, nursing needs were not documented in the chart by the nursing staff. (Standard not met.)

2009 Findings: All charts reviewed contained an initial nursing assessment which was very comprehensive. Nursing needs were documented; however, specific care plans were not written on the nursing assessment form. (Standard met.)

Standard: All patients are reassessed at appropriate intervals to determine their response to treatment and to plan for continued treatment or discharge.

2006 Findings: Nursing reassessments (flowcharts) were sometimes left blank, but there were daily nursing notes for the patients. Nurses indicated time as the major factor preventing the documentation of reassessments each shift. (Standard not met.)

2009 Findings: All charts reviewed contained a thorough nursing assessment for each shift. (Standard met.)

Standard: *Qualified individuals conduct the assessments and reassessments and have their responsibilities defined in writing.*

2006 Findings: The policy for assessments and reassessments was not available. (Standard not met.)

2009 Findings: Both professional and auxiliary nurses conduct patient assessments. The nurse educator provides instruction on physical assessment skills during orientation and also as a continuing education class. Their responsibilities are defined in their job descriptions. (Standard met.)

3. Care of Patients

Standard: *There is a process to integrate and coordinate the care provided to each patient.*

2006 Findings: There was no evidence that interdepartmental rounds or conferences which include nursing staff are conducted, and there was no evidence of a written nursing care plan. (Standard not met.)

2009 Findings: Interdepartmental rounds occur daily and a nurse is in attendance. Often the disciplines represented are limited to medicine and nursing, other disciplines attend but not daily. Although there were excellent nursing assessments and nursing notes charted there were no written nursing care plans in the charts reviewed. (Standard partially met.)

Standard: *Policies and procedures guide the care of high risk patients and the provision of high risk services. Staff members have been trained and use the policies and procedures to guide care.*

2006 Findings: No policies and procedures for the care of high risk patients were available. (Standard not met.).

2009 Findings: A policy and procedure manual was available with policies related to infection control, vital signs, blood products, chemotherapy, central and peripheral lines. The manual had been reviewed by the head nurse, signed and dated. (Standard met.).

Standard: *Medication use in the organization is efficiently organized to meet patient needs.*

2006 Findings: There was no policy found for administering chemotherapy, and no formal training and competencies were required for

administration of chemotherapy. Chemotherapy is not always administered by a registered nurse. There are many occasions when a technical nurse administers chemotherapy, and the qualifications of these nurses were not documented. Medications are stored on carts and refrigerators in the patient hallway. The environment, while clean, is very crowded. The security of medications in this semi-public area is questionable. Nurses stated that the patient's armband was checked and it was noted that the medications from pharmacy were labeled. There was no policy available to confirm the process. There was also no policy for reporting medication errors. (Standard not met.)

2009 Findings: There are specific policies for administering chemotherapy drugs. There is a formal training program for nurses, and there is an evaluation process to determine competence. Medications are stored properly and labeled. Patients wore armbands and the nurses used the armband as a method of patient identification. There is a process for reporting medication errors. (Standard met.)

Standard: The organization addresses end of life care.

2006 Findings: A staff physician has begun an outstanding palliative care initiative which is interdisciplinary and involves the nursing staff. The nursing staff expressed awareness of the unique needs of these patients. (Standard met.)

2009 Findings: The nursing staff continues to be actively involved in the palliative care program directed. Palliative care education for nurses was documented. (Standard met.)

Standard: Pain is assessed in all patients.

2006 Findings: The nursing staff stated that patients were assessed for pain on an ongoing basis; however, documentation did not confirm that this was done. (Standard not met.)

2009 Findings: In the nursing assessment form there is a section for pain assessment using a pain scale. In every chart reviewed, pain level of the patient was documented for each shift. (Standard met.)

Standard: Patients are supported in managing pain effectively.

2006 Findings: Pain medication administration was not consistently documented. (Standard not met.)

2009 Findings: Pain medication administration was documented on all charts reviewed. (Standard met.)

Standard: Patients are educated about pain, other symptoms, and managing pain and symptoms as part of the treatment.

2006 Findings: There was no documentation to support education of patients and families about pain management. (Standard not met.).

2009 Findings: There was no documentation of patient or family education regarding pain. (Standard not met.).

4. Patient and Family Education

Standard: Each patient's educational needs are assessed and recorded in his or her record.

2006 Findings: The registered nurse dedicated to the role of patient and family education stated that her education focused on newly diagnosed patients and families and home visits for educational purposes were provided when indicated. Although the educator stated that education was provided there was no documentation recorded on the chart. (Standards not met.)

2009 Findings: A full time nursing position is dedicated to patient and family education; however, there was no evidence (documentation) of patient and family education on any chart reviewed. The head nurse stated that the educator has been asked to document her work but has not done so. (Standard not met.)

Standard: Patient and family education includes the following topics, as appropriate to the patient's care: the safe use of medications, the safe use of medical equipment, potential interactions between medications and food, nutritional guidance, and rehabilitation techniques.

2006 Findings: The educator stated that medication and nutrition education was taught; however, there was no documentation of education in the charts reviewed. (Standard not met.)

2009 Findings: There was no documentation of any patient education. (Standard not met.)

5. Prevention and Control of Infections

Standard: The organization designs and implements a coordinated program to reduce the risk of nosocomial infections in patients and health care workers.

2006 Findings: There is a nurse designated as the infection control nurse. She was trained on the job to perform her responsibilities. She monitors surveillance activities and reports findings monthly to the medical director. These reports were not available for review. There are isolation rooms to help prevent

the spread of communicable disease and to isolate vulnerable patients. Due to space constraints, the rooms on the general unit are semi-private. All units were clean and there was constant evidence of housekeeping personal cleaning all areas. The nurses reported that they have difficulty obtaining antibacterial soap, and alcohol gel is practically never used. There was no documented education related to prevention and control of infections. (Standard not met.)

2009 Findings: There are 3 full time infection control employees, 2 nurses and a physician. All have completed a 4 week comprehensive infection control course directed by the IOP Infection Control Program. All rooms were clean and had hand sanitizer available. In the new hospital addition (currently under construction) all patient rooms will be private. Documentation of infection control teaching done by the nurse educator was available. (Standard met.)

6. Staff Qualifications and Education

Standard: Each staff member's responsibilities are defined in a current job description.

2006 Findings: The nursing job descriptions that defined responsibilities were under revision by the human resources department, the hospital administrator and the nursing director. (Standard partially met.)

2009 Findings: There were recently revised job descriptions that clearly defined nursing responsibilities. The head nurse had access to all nursing job descriptions. (Standard met.)

Standard: The organization uses a defined process to ensure that staff knowledge and skills are consistent with patient needs.

2006 Findings: There was no process to evaluate clinical competencies. (Standard not met.)

2009 Findings: Chemotherapy and central line care classes were provided and competency for these skills was evaluated and documented in each nurse's education folder. Competency was defined by an evaluation score of 70% or greater. (Standard met.)

Standard: A staffing plan for the organization, developed collaboratively by the clinical and managerial leaders, identifies the number, types, and desired qualifications of staff.

2006 Findings: A staffing plan was requested but not received. A very general overview of staffing was presented by the head nurse. There was no evidence that assignments were based on scope and frequency of care required and skill level of nurse. (Standard not met.)

2009 Findings: A staffing plan was available for review. The plan was completed by the head nurse in cooperation with the unit managers. The plan was detailed and very well organized. Staffing has improved since 2006 and is in accordance with the recommended nurse patient ratio for pediatric oncology patients. (Standard met.).

Standard: All staff members are oriented to the organization and to their specific job responsibilities at appointment to the staff.

2006 Findings: There was no organized education for newly hired nurses. Nurses were provided 15 days of orientation and during this time they worked with a preceptor to understand roles and responsibilities. Nurses are not paid during the orientation period. Theory and clinical skills were not taught or evaluated. Based on the nursing staff's description of the process, new nurses are given a full assignment after this orientation time. (Standard not met.)

2009 Findings: A comprehensive well organized pediatric oncology education program was provided to all new nursing staff. The program consisted of 5 consecutive days of documented theoretical presentations and 5 consecutive days of documented clinical experience with a preceptor. All orientation education, including evaluation scores, was documented in each nurse's education record. A policy was instituted in 2007 to pay nurses for their time spent in orientation. (Standard met.)

Standard: Each staff member receives ongoing in-service and other education and training to maintain or advance his or her skills or knowledge.

2006 Findings: There is a monthly education and training session for the nursing staff developed by nursing leadership in collaboration with the medical staff. There is not a written plan for this, and there is no process for ensuring that all nursing staff members are included. Per the nurses' report, ICU nurses have had PAL's training. (Standard not met.)

2009 Findings: Organized continuing education classes were available for all nurses. Classes were organized by the nurse educator and included relevant pediatric oncology topics. All classes were well documented and included topic presented, presenter, time and date, persons in attendance, and evaluation score of each nurse. All information was documented in each nurse's education chart. Hard copies of the evaluation exams were also filed in each education chart. (Standard met.)

Organizational Specific Aim 2 compared the patient to nurse ratio pre program implementation to post program. Patient to nurse ratio in 2006 (pre GNP) was determined by staff interviews and direct observation of the day shift on the general unit of the Guatemalan partner site. The same process was used in 2009. In addition, the number of

new full time pediatric oncology nursing staff positions (professional and technical) created post program implementation was obtained from Human Resources. Technical nurses are given patient assignments similar to professional nurses and were therefore included in calculating the patient to nurse ratio.

In 2006, the patient to nurse ratio was 6 to 8 (average 7) for the day shift in the general unit. In 2009, the patient to nurse ratio was 4 to 6 (average 5) for the day shift in the general unit. In 2007, 10 (7 professional, 3 technical) nursing staff positions were created. In 2008, 14 (9 professional, 6 technical) nursing staff positions were created, and in 2009 no staff positions were created. From 2006 to 2009, the number of inpatient beds and the occupancy rate remained stable. **Table 4.4** includes the patient to nurse ratio and number of nursing positions pre and post GNP.

Clinical Outcomes

Clinical outcomes included event free survival (EFS) and the cumulative incidence of treatment abandonment within the first year of diagnosis. Pre GNP clinical outcomes were compared to post GNP outcomes within the intervention site (Guatemala) and to the control site (Honduras). The pre GNP time period included patients diagnosed between January 01, 2004 and December 31, 2006; the post GNP time period included patients diagnosed between January 01, 2007 and October 1, 2008. Comparisons were done on all cancer patients and on a subgroup of patients with acute lymphoblastic leukemia.

Patients at IOP's partner sites in Guatemala and Honduras diagnosed with cancer between January 1, 2004 and October 1, 2008 and registered in POND were included in the study. For both sites, the sample size for all cancer diagnoses was 1,936 patients (Guatemala, 1145; Honduras, 791) and for acute lymphoblastic leukemia was 923 patients (Guatemala, 513; Honduras, 410). The pre GNP sample size for all cancer diagnoses was 1286 (Guatemala, 730; Honduras, 486) and the post GNP sample size was 720 (Guatemala, 415; Honduras, 305). The pre GNP sample size for acute lymphoblastic leukemia patients was 588 (Guatemala, 336; Honduras, 252) and the post GNP sample size was 335 (Guatemala, 177; Honduras, 158). Chi-square and Wilcoxon rank sum tests were used to compare the distribution of cancer diagnoses and the differences in age at time of diagnosis between sites. Among all cancer patients, the distribution of cancer diagnoses was statistically significantly different ($p < 0.0001$) between sites. For all cancers, the mean age at time of cancer diagnosis was statistically significantly different ($p = 0.0092$) between sites. For acute lymphoblastic leukemia patients the mean age at time of diagnosis was not statistically significantly different ($p = 0.4759$) between sites. **Table 4.5** compares the distribution of cancer diagnoses between sites and **Table 4.6** compares the age at time of diagnosis for all patients and for acute lymphoblastic leukemia patients between sites.

Clinical Specific Aim 1 compared the pre/ post GNP EFS distributions (with relapse or death classified as events) in Guatemala for all cancer patients and for acute

Table 4.4. Patient to Nurse Ratio and Number of Nursing Positions Pre/Post Guatemalan Nursing Program (GNP)

Nurse Staffing	Pre GNP	Post GNP
Patient Nurse Ratio^a	7 : 1	5 : 1
Nursing Positions^b	88	112
Professional nurse	40	56
Technical nurse	48	57
Inpatient Beds	37	37
Occupancy Rate (%)	95-100	95-100

^a General unit day shift

^b Full-time staff positions

Table 4.5 Distribution of Cancer Diagnoses for Guatemala and Honduras

Cancer Types	Total		Sites				p-Value
			Guatemala		Honduras		
	Freq	Perc	Freq	Perc	Freq	Perc	
Acute lymphoblastic leukemia	923	47.68	513	44.8	410	51.83	<0.0001
Acute myelogenous leukemia	133	6.87	70	6.11	63	7.96	
Ewing sarcoma	34	1.76	32	2.79	2	0.25	
Germ cell tumor	50	2.58	45	3.93	5	0.63	
Hepatoblastoma	30	1.55	27	2.36	3	0.38	
Hodgkin lymphoma	224	11.57	124	10.83	100	12.64	
Neuroblastoma	29	1.5	15	1.31	14	1.77	
Non-Hodgkin lymphoma	117	6.04	68	5.94	49	6.19	
Osteosarcoma	84	4.34	51	4.45	33	4.17	
Retinoblastoma	171	8.83	129	11.27	42	5.31	
Rhabdomyosarcoma	62	3.2	40	3.49	22	2.78	
Wilms tumor	79	4.08	31	2.71	48	6.07	

Table 4.6 Comparison of Age at Diagnosis for All Cancer Diagnoses and for Acute Lymphoblastic Leukemia in Guatemala and Honduras

Age at Diagnosis (Yrs)	N	Min	5% Quartile	Median	95% Quartile	Max	Mean	SD	p-Value
All Cancer Diagnoses									
Total	1936	0.00	0.92	6.54	15.58	23.58	7.35	4.64	0.0092
Guatemala	1145	0.00	0.83	6.33	15.33	19.17	7.11	4.56	
Honduras	791	0.08	1.42	6.92	16.08	23.58	7.69	4.74	
Acute Lymphoblastic Leukemia									
Total	923	0.00	1.92	7.00	15.58	17.83	7.76	4.42	0.4759
Guatemala	513	0.00	1.50	6.92	15.33	17.83	7.62	4.25	
Honduras	410	0.08	2.08	7.08	16.00	17.83	7.94	4.62	

lymphoblastic leukemia patients (within site comparison). For Guatemala, the pre GNP EFS for all cancer patients (1- year EFS estimate: 70.98 ± 1.91) was not statistically significantly different from the post GNP EFS (1-year EFS estimate: 70.68 ± 2.71) (p-value from log-rank test = 0.18). The pre GNP EFS for acute lymphoblastic leukemia patients (1-year EFS estimate: 72.59 ± 2.53) was also not statistically significantly different from post GNP EFS (1-year EFS estimate 79.64 ± 3.12) (p-value from log rank = 0.29). **Figure 4.1** shows the Kaplan Meier EFS distributions for Guatemalan cancer patients pre (04-06) and post (07-08) GNP, and **Figure 4.2** shows the Kaplan Meier EFS distributions for Guatemalan acute lymphoblastic leukemia patients pre (04-06) and post (07-08) GNP.

Clinical Specific Aim 2 compared the pre/post GNP EFS distributions for all cancer patients between the intervention site in Guatemala and the control site in Honduras. For all cancer diagnoses, the pre GNP EFS for Guatemala (1-year EFS estimate: 70.98 ± 1.9) was statistically significantly lower than that of Honduras (1-year EFS estimate: 76.77 ± 2.12) (p-value from log-rank test = 0.011). The post GNP EFS for Guatemala (1-year EFS estimate 70.68 ± 2.7) was also statistically significantly lower than that of Honduras (1-year EFS estimate: 81.19 ± 2.53) (p-value from log-rank test = 0.0001). **Figure 4.3** shows the Kaplan Meier EFS distributions for all cancer diagnoses pre GNP (04-06) for Guatemala and Honduras, and **Figure 4.4** shows Kaplan Meier EFS distributions for all cancer diagnoses post GNP (07-08) for Guatemala and Honduras.

Clinical Specific Aim 3 compared the pre/post GNP EFS distributions for acute lymphoblastic leukemia cancer patients between the intervention site in Guatemala and the control site in Honduras. For acute lymphoblastic leukemia patients, the pre GNP EFS for Guatemala (1-year EFS estimate: 72.59 ± 2.53) was not statistically significantly different than that of Honduras (1-year EFS estimate: 79.96 ± 2.71) (p-value from log-rank test = 0.074). The post GNP EFS for Guatemala (1-year EFS estimate 79.64 ± 3.12) was also not statistically significantly different than that of Honduras (1-year EFS estimate: 86.09 ± 3.10) (p-value from log-rank test = 0.18). **Figure 4.5** shows the Kaplan Meier EFS distributions for acute lymphoblastic leukemia patients pre GNP (04-06) for Guatemala and Honduras. **Figure 4.6** shows Kaplan Meier EFS distributions for acute lymphoblastic leukemia post GNP (07-08) for Guatemala and Honduras.

Clinical Specific Aim 4 compared the GNP pre/post CIN (cumulative incidence) of treatment abandonment in Guatemala within the first year of diagnosis for all cancer patients and for acute lymphoblastic leukemia patients. For all cancer diagnoses, the pre GNP CIN of abandonment (10.17 ± 1.17) was statistically significantly higher ($p = .045$) than the post CIN (6.45 ± 1.32). For acute lymphoblastic leukemia patients only, the pre CIN of abandonment (9.09 ± 1.58) was also higher than the post CIN (05.67 ± 1.75) but was not significantly different ($p = 0.1875$). **Figure 4.7** presents CIN of abandonment for all cancer patients diagnosed in Guatemala between January 01, 2004 and December 31, 2006 ($N = 730$) to those diagnosed between January 01, 2007 and October 01, 2008 ($N = 412$). **Figure 4.8** presents CIN of abandonment for acute lymphoblastic leukemia patients diagnosed in Guatemala between January 01, 2004 and December 31, 2006 ($N = 336$) to those diagnosed between January 01, 2007 and October 01, 2008 ($N = 177$).

Figure 4.1 Kaplan Meier EFS Distributions for Guatemalan Cancer Patients Pre (04-06) and Post (07-08) GNP

Figure 4.2 Kaplan Meier EFS Distributions for Guatemalan Acute Lymphoblastic Leukemia Patients Pre (04-06) and Post (07-08) GNP

Figure 4.3 Kaplan Meier EFS Distributions for All Cancer Diagnoses Pre GNP (04-06) for Guatemala and Honduras

Figure 4.4 Kaplan Meier EFS Distributions for All Cancer Diagnoses Post GNP (07-08) for Guatemala and Honduras

Figure 4.5 Kaplan Meier EFS Distributions for Acute Lymphoblastic Leukemia Pre GNP (04-06) for Guatemala and Honduras

Figure 4.6 Kaplan Meier EFS Distributions for Acute Lymphoblastic Leukemia Post GNP (07-08) for Guatemala and Honduras

Figure 4.7 CIN of Abandonment for All Cancer Patients Diagnosed in Guatemala Pre GNP (04-06) to Those Diagnosed Post GNP (07-08)

Figure 4.8 CIN of Abandonment for Acute Lymphoblastic Leukemia Patients Diagnosed in Guatemala Pre GNP (04-06) to Those Diagnosed Post GNP (07-08)

Clinical Specific Aim 5 compared the pre/post GNP CIN of treatment abandonment within the first year of diagnosis for all cancer patients between the intervention site in Guatemala and the control site in Honduras (control site comparison).

For all cancer patients, the pre GNP CIN of abandonment for Guatemala (10.17 ± 1.17) was marginally lower ($p = 0.0536$) than the CIN for Honduras (13.69 ± 1.59). The post GNP CIN for Guatemala (6.45 ± 1.32) was statistically significantly lower ($p = 0.0003273$) than Honduras (14.65 ± 2.7). **Figure 4.9** compares the CIN of abandonment between Guatemala and Honduras for all patients diagnosed between January 01, 2004 and December 31, 2006 (Guatemala, $N = 730$; Honduras, $N = 485$). **Figure 4.10** compares the CIN of abandonment between Guatemala and Honduras for all patients diagnosed between January 01, 2007 and October 1, 2008 (Guatemala, $N = 412$; Honduras $N = 303$).

Clinical Specific Aim 6 compared the pre/post GNP CIN of treatment abandonment within the first year of diagnosis for patients with acute lymphoblastic leukemia between the intervention site in Guatemala and the control site in Honduras (control site comparison). For acute lymphoblastic leukemia patients, the pre GNP CIN for Guatemala (9.09 ± 1.58) was not statistically different ($p = 0.2335$) from the CIN for Honduras (11.92 ± 2.08); however, the post GNP CIN for Guatemala (5.67 ± 1.75) was statistically significantly lower ($p = 0.01754$) than the CIN for Honduras (13.30 ± 2.78). **Figure 4.11** compares the CIN of abandonment between Guatemala and Honduras for acute lymphoblastic leukemia (ALL) patients diagnosed between January 01, 2004 and December 31, 2006 (Guatemala, $N = 336$; Honduras, $N = 251$). **Figure 4.12** compares the CIN of abandonment between Guatemala and Honduras for acute lymphoblastic leukemia patients diagnosed between January 01, 2007 and October 1, 2008 (Guatemala, $N = 177$; Honduras, $N = 157$).

Figure 4.9 CIN of Abandonment Comparison between Guatemala and Honduras for All Patients Diagnosed Pre GNP (04-06)

Figure 4.10 CIN of Abandonment Comparison between Guatemala and Honduras for All Patients Diagnosed Post GNP (07-08)

Figure 4.11 CIN of Abandonment Comparison between Guatemala and Honduras for Acute Lymphoblastic Leukemia Patients Diagnosed Pre GNP (04-06)

Figure 4.12 CIN of Abandonment Comparison between Guatemala and Honduras for Acute Lymphoblastic Leukemia Patients Diagnosed Post GNP (07-08)

CHAPTER 5: DISCUSSION

In 2006, the quality of nursing care at St. Jude's partner site in Guatemala was assessed using standards from six Joint Commission International (JCI) quality domains. Quality standards were found lacking in all six domains; however, the most critical needs with relevance to nursing were identified in the domain of Staff Qualifications and Education. In 2007, the Guatemalan Nursing Program (GNP) was implemented to promote quality pediatric oncology nursing care. The primary focus of the program was to improve nursing education and staffing, and a secondary focus was to improve all quality standards with relevance to nursing. This research study was designed to evaluate the GNP's fidelity and impact on staff, organizational, and clinical outcomes. Logic model theory provided the conceptual framework for both the development and evaluation of the GNP. This chapter discusses the study's results, significance, strengths, limitations, and the future direction for research.

Study Results

Program Fidelity

Two critical aspects of program fidelity were the preparation and support provided to the educator, and a process evaluation to determine how well the education responsibilities were operationalized. These aspects of the GNP were well documented. Determining program fidelity was a critical first step for this study since a causal relationship with staff, organizational, and clinical outcomes could only be determined if the program was implemented as designed. Preparation and support for the educator was essential for the GNP's success and for the fidelity of the program. A full time nurse educator dedicated to a specific hospital unit was a new concept for Guatemala, where a large public hospital typically has only one educator. Because of the novelty of the role, there were no local role models to mentor the educator. The newly hired educator was an experienced nurse but had no formal pediatric oncology education and only limited experience in teaching. Clearly, the educator needed professional support to succeed in this pioneering role. The Latin American Center for Pediatric Oncology Nursing Education in Santiago, Chile was created to meet the needs of nurse educators throughout Latin America. Development of the Center began in 2007; however, it was not fully operational until early 2008. The Guatemalan nurse educator was hired in 2007, and on site education was organized by the International Outreach Program (IOP) nursing director and the medical director in Guatemala. In 2008, the nurse educator completed a 4-week comprehensive educator course taught at the Center. The course's structure included four components: pediatric oncology lectures, instruction in the use of educational resources, and teaching methodology, a self-directed project, and direct observation of patient care. Professional support was consistently provided to the educator. The Guatemalan nurse educator, along with other Latin American pediatric oncology educators, attended bimonthly Horizon Live web meetings that provided

ongoing education, support, and mentoring. The IOP nursing director had a monthly telephone conference with the educator to provide individual support and identify any administrative issues that needed attention. To ensure that the educator received institutional support, the IOP nursing director worked closely with the medical and administrative directors in Guatemala.

Operationalization of the Education Component

Also essential to the fidelity of the program was how well the education component was operationalized. A process evaluation was done and included a description of the educational content and the number of education activities provided by the nurse educator. The focus of this evaluation was on what the educator provided; staff outcomes related to education were evaluated separately. The educator provided: a pediatric oncology nursing education course for newly hired nurses to all 25 of the professional nurses hired after program implementation (January 1, 2007); a chemotherapy course to 45 of the 49 professional nurses; a central venous line care course to 29 of the 49 professional nurses; and during year 2008, provided 56 educational presentations totaling 134.5 hours of continuing education. Although this process evaluation was conducted as part of the study, process evaluation began with program inception and continues on a regular basis through monthly reports documenting education activities provided.

Staff Outcomes

One of the key principles of successful treatment of childhood cancer is the provision of specialized professional care in pediatric cancer units (Wagner & Antic, 1997; McGregor, et al., 2007). A major impediment to successful cancer treatment in developing countries is the lack of education and training for nurses, the largest group of health care professionals (Barr et al., 2006). This study substantiated that prior to program implementation a lack of education for pediatric oncology nurses existed in Guatemala. This study also demonstrated that a nurse educator can positively impact staff outcomes related to pediatric oncology education.

Forty-nine nurses met the defining criteria for professional staff nurse and all were included in the study. Pediatric oncology treatment in Guatemala is only available at the IOP partner site, thus the staff nurses included in the study technically represented the pediatric oncology staff nurse population for the country. The sample was homogeneous, with 94% female and 98% diploma graduates. Their mean length of employment at the partner site was 3.5 years (range 0.5 - 9.6). There was an even split of nurses hired pre program implementation (24, 51%) and those hired post program implementation (25, 49%).

The GNP's impact on staff outcomes was evaluated by comparing the percentage of nurses receiving education pre program implementation to the percentage of those

receiving education post program implementation. In addition evaluation scores and continuing education hours were compared to desired outcomes or benchmark values.

Staff Specific Aim 1 compared the percentage of nurses hired post program implementation that successfully completed a pediatric oncology education course for newly hired nurses to an expectation of 100% completion rate. This education course was designed specifically for newly hired nurses and was not available for nurses hired prior to program implementation. Twenty five nurses were hired post program implementation, and all 25 completed the course. The mean evaluation score was 86.14 ± 7.43 (range 70-97 %). The 24 nurses hired prior to program implementation did not receive any clinical or theoretical education designed for newly hired nurses. Their education consisted of 15 days spent with another staff nurse; however, this time was considered a trial period and was without pay.

Staff Specific Aim 2 compared the percentage of nurses competent in central venous line care to pre program percentages. No nurses completed a central venous line care course pre program implementation. Post program implementation, twenty-eight nurses (57%) participated in the course and 22 (45%) successfully completed the course. Of the 28 participants, the mean evaluation score was 77.93 ± 14.73 (range 46-98 %).

Staff Specific Aim 3 compared the percentage of nurses competent in chemotherapy administration to pre program percentages. Again, no nurses completed a chemotherapy administration course pre program implementation. Post program implementation, 42 nurses (86%) participated in the course, and 39 (80%) successfully completed the course. Of the 42 participants, the mean evaluation score was 86.64 ± 9.74 (range 62-100). Eighty per cent of the nursing staff completed the chemotherapy administration course compared to only 45% of nurses who completed the central venous line care course.

Competency in chemotherapy administration was seen as a priority and given a stronger emphasis than central line care competency and thus contributed to these results. In Guatemala, as in many developing countries, not all patients have a central venous line; however, every child receives chemotherapy.

Staff Specific Aim 4 compared the mean annual hours of continuing education for year 2008 to the annual hours (10) of continuing education required for APHON certification. The mean annual hours of continuing education for 2008 (21.21 ± 8.04) was statistically significantly greater ($p < 0.0001$) than the 10 hours required for APHON certification. During the 2006 nursing assessment prior to program implementation, it was reported that a monthly educational presentation was provided to the nurses, but this was not documented.

Pediatric oncology education for newly hired nurses, central venous line care courses, chemotherapy administration courses, and continuing education classes were not provided prior to program implementation. However, in 2002, 3 nurses in the sample attended a training school for pediatric oncology nurses in El Salvador, which offered a

12-week course in theory and clinical practice. Unfortunately in 2003, after 4 years of operation the school was closed because of financial concerns and the inability for many nurses to commit to 12 weeks away from home (Wilimas et al., 2003).

Numerous factors contributed to the lack of education prior to program implementation. There was no organized approach to education and no one was given dedicated time or support to provide education. The head nurse was technically responsible for educating newly hired nurses, but her additional responsibilities which included management of housekeeping and administrative support personnel, posed a major obstacle. In addition, the nursing department was dependent on leaders from medical and administrative departments for financial support, and these leaders did not see education for nurses as an important need.

The nurse educator succeeded in positively impacting staff educational outcomes for several reasons. The educator was provided education, resources, and support needed to succeed in this new role. Basic management principles played a role in the educator's success. The educator's role was clearly defined, and the education responsibilities were closely monitored. The IOP nursing director maintained close contact with the educator, the medical director, and the administrative director and interceded quickly when problems were identified. Of all the factors influencing staff outcomes, the most important one was the dedication of the nurse educator to providing quality staff education.

Not all professional nurses successfully completed the chemotherapy and central venous line care courses. After the 2009 quality assessment, a plan was developed to ensure that within the next 12 months competencies would be attained in chemotherapy and central venous line care by all nurses. It will be important to continue to evaluate clinical outcomes to determine the impact of having competencies met in both areas by all the professional nurses. It should also be noted that in Guatemala, the responsibilities of the professional nurse and technical nurse are very similar. Both technical and professional nurses provide direct patient care and administer medications including chemotherapy. One main difference is that only professional nurses can assume management roles. For this study, only professional nurses were included in the evaluation of staff outcomes; however, the nurse educator provided the same educational content to technical nurses because of their similar patient care roles.

Organizational Outcomes

The primary focus of the GNP was to improve nursing education and staffing. A secondary focus was to improve all JCI quality standards relevant to nursing (Day, et al., 2008). Compared to pre program results, the number of JCI standards met post program increased considerably.

Organizational Specific Aim 1 compared the percentage of JCI nursing quality standards met pre GNP implementation to post program percentages. The nursing quality

assessment provided the data to evaluate the JCI standards. The same process used to conduct the initial nursing assessment done in 2006 was used to conduct the 2009 post intervention assessment and the same 20 standards within the 6 designated JCI domains were evaluated. Standard results were reported as met, partially met, or not met. In 2006, of the 20 standards measured, only 1 (5%) standard was met, 2 (10%) were partially met, and 17 (85%) were not met. In 2009, the same 20 standards were measured, and 16 (80%) were met, 1 (5%) was partially met, and 3 (15%) were not met.

These results can be attributed to several factors. The nursing quality assessment served as the foundation for the development of the GNP. The findings provided the baseline from which nursing needs and recommendations were determined. Most important, the assessment provided objective and credible findings and an organizational framework for implementing change. In addition the assessment results gave focus to specific areas that needed improvement. Another important factor was that the JCI assessment was valued by medical and administrative leaders in Guatemala. JCI standards are universally recognized as the gold standard for international accreditation and the process of accreditation has gained international acceptance as an effective quality evaluation and management tool. These facts captured the attention of the partner site leaders who possessed the authority and financial access to support the nursing program. After reviewing the initial assessment results, partner site leaders committed to supporting efforts to improve nursing standards. The medical, administrative, and nursing staff worked together as a team to improve nursing standards. Without an interdisciplinary team approach efforts to improve nursing standards would not have succeeded. Although the number of standards met post program implementation improved, several standards remained not met or only partially met. The post program assessment report provided a plan to meet those standards and that plan is currently in place.

Organizational specific aim 2 compared the patient to nurse ratio pre program implementation to post program. In 2006, the patient to nurse ratio was 6 to 8 (average 7) patients per nurse for the day shift in the general unit. In 2009, the patient to nurse ratio was 4 to 6 (average 5) patients per nurse for the day shift in the general unit. Technical nurses are given patient assignments similar to professional nurses and were therefore included in calculating the patient to nurse ratio. In 2007, 10 (7 professional, 3 technical) nursing staff positions were created, in 2008, 14 (9 professional, 6 technical) nursing staff positions were created, and in 2009 no staff positions were created. From 2006 to 2009, the number of inpatient beds and the occupancy rate remained stable.

Improving patient to nurse ratio required support from leaders at the partner site and at the local non- governmental philanthropic foundation. To obtain the financial commitment needed to improve patient to nurse ratio the value of nursing needed to be advanced. A presentation on the “Value of Nursing” was given to medical and administrative leaders and to the foundation’s board of directors. The presentation was evidence based and included statistics from research conducted by Aiken, Clarke, Sloane, Sochalski, & Silber (2002) and Needleman et al. (2002). The evidence that the patient nurse ratio impacts mortality was a new concept to the audience and prompted many

questions. The well documented evidence published in journals revered by the medical staff was the impetus for a change in attitude. Overall, the evidence based approach to validating the need for more nurses helped gain the financial support needed to create more nursing positions

Clinical Outcomes

Clinical Specific Aims 1 through 3 sought to determine if the GNP was associated with improved EFS. Aims 4 through 6 sought to determine if the GNP was associated with CIN (cumulative incidence) of treatment abandonment within the first year of diagnosis. The study did not find an association with improved EFS but did find a statistically significant association with an improved CIN of treatment abandonment within the first year of diagnosis.

The clinical sample included all patients at IOP's partner sites in Guatemala and Honduras diagnosed with cancer between January 1, 2004 and October 1, 2008 and registered in POND. Pediatric oncology treatment for Guatemala and Honduras is only available at the IOP partner sites; therefore, the sample essentially represented the population of pediatric oncology patients for both countries. The sample size for all cancer diagnoses was 1,936 patients (Guatemala, 1145; Honduras, 791), and for acute lymphoblastic leukemia was 923 patients (Guatemala, 513; Honduras, 410). Guatemala has a higher population than Honduras (Guatemala, 12.7 million, Honduras, 8 million) and this accounted for the differences in number of patients diagnosed between sites. Among all cancer patients, the distribution of cancer diagnoses was statistically significantly different between sites, and the mean age at time of cancer diagnosis was also statistically significantly different between sites. However, for acute lymphoblastic leukemia patients, the mean age at time of diagnosis was not statistically significantly different between sites and, as expected, represented a more homogenous group for comparison.

Clinical Specific Aim 1 compared pre and post GNP EFS in Guatemala for all cancer diagnoses and for acute lymphoblastic leukemia. Clinical Specific Aim 2 compared the pre/post GNP EFS for all cancer patients between Guatemala and Honduras, and Clinical Specific Aim 3 compared the pre/post GNP EFS for acute lymphoblastic leukemia between Guatemala and Honduras.

Unfortunately, the GNP was not associated with statistically significant improvements in EFS. For Guatemala, the pre GNP EFS for all cancer patients was not statistically significantly different from the post GNP EFS ($p = 0.18$). The pre GNP EFS for acute lymphoblastic leukemia patients was also not statistically significantly different from post GNP EFS ($p = 0.29$). For all cancer diagnoses, the pre GNP EFS for Guatemala was statistically significantly lower than that of Honduras ($p = 0.011$), and the post GNP EFS for Guatemala remained statistically significantly lower than that of Honduras ($p = 0.0001$). For acute lymphoblastic leukemia patients, the pre GNP EFS for Guatemala was not statistically significantly different than that of Honduras ($p = 0.074$). The post GNP

EFS for Guatemala was also not statistically significantly different than that of Honduras ($p = 0.18$).

Several factors may have contributed to these findings. The post program time period included patients diagnosed between January 01, 2007 and October 01, 2008. No patients registered in POND after the date of IRB approval (October 2008) were entered into the study; therefore, October 01, 2008 was the post program cutoff date to allow a full year of patient follow up and resulted in a post program follow up time period of 12 to 18 months. The most accurate indicator for pediatric oncology survival is the 5-year EFS probability and is the endpoint used in the majority of research studies (Pui, et al., 2009). Preferably, the post program EFS should have been followed for a full 5 years to provide a more complete indicator of survival.

A major obstacle to conducting research in developing countries is limited access to data, and this study was no exception. Data for traditional nurse-sensitive measures, such as nosocomial infection rates, central venous line and chemotherapy complications, and pain management were not available. Landmark studies linking nursing education and staffing with decreased mortality had access to large patient data bases from multiple hospitals and used regression analysis to control for patients' risk of adverse outcomes and other variables (Aiken, Clarke, & Sloane, 2002; Needleman, et al., 2002). The data needed in this study to stratify patients based on disease severity or control for other confounding variables was not available. Although the group of patients with acute lymphoblastic leukemia provided the most homogeneous group for comparison, ideally these patients should have been further subdivided into severity groups.

Clinical Specific Aims 4 through 6 found a statistically significant association between the GNP and the CIN (cumulative incidence) of treatment abandonment within the first year of diagnosis. Clinical Specific Aim 4 compared the GNP pre/post CIN of treatment abandonment for all cancer patients and for acute lymphoblastic leukemia patients in Guatemala. Post program CIN of abandonment improved for both groups of patients. For all cancer diagnoses, the pre GNP CIN of abandonment (10.17 ± 1.17) was statistically significantly higher ($p = 0.045$) than the post CIN (6.45 ± 1.32). For acute lymphoblastic leukemia patients only, the pre CIN of abandonment (9.09 ± 1.58) was also higher than the post CIN (5.67 ± 1.75) although not significantly different ($p=0.1875$). Clinical Specific Aim 5 compared the pre/post GNP CIN of treatment abandonment for all cancer patients between the intervention site in Guatemala and the control site in Honduras, and Clinical Specific Aim 6 compared the pre/post GNP CIN of treatment abandonment for patients with acute lymphoblastic leukemia between the intervention site in Guatemala and the control site in Honduras. For all cancer patients, the pre GNP CIN of abandonment for Guatemala (10.17 ± 1.17) was marginally lower ($p = 0.0536$) than the CIN for Honduras (13.69 ± 1.59). The post GNP CIN for Guatemala (6.45 ± 1.32) was statistically significantly lower ($p = 0.0003273$) than Honduras (14.65 ± 2.7). For acute lymphoblastic leukemia patients, the pre GNP CIN for Guatemala (9.09 ± 1.58) was not statistically different ($p = 0.2335$) from the CIN for Honduras (11.92 ± 2.08); however, the post GNP CIN for Guatemala (5.67 ± 1.75) was statistically significantly lower ($p = .01754$) than the CIN for Honduras (13.30 ± 2.78).

Abandonment of treatment (4 weeks of missing appointments during active treatment) is a critical problem in developing countries. Numerous studies have looked at causes of abandonment. A study by Metzger et al. (2003) systematically attempted to determine factors relating to abandonment and concluded that abandonment was associated with prolonged travel time to the treatment facility. A systematic review of medical literature for evidence on causes of abandonment and interventions was conducted by Arora et al. (2007). The authors concluded that abandonment is related to socio-economic and educational status of parents, travel time to treatment centers, and affordable and locally available treatment, and that twinning between institutions has been shown to be effective in decreasing abandonment. This is the first study to attempt to determine the relationship between abandonment of treatment in developing countries and interventions specifically related to nursing.

Several factors may have contributed to the study's findings. The GNP provided extensive pediatric oncology education for the nursing staff and this education positively influenced their ability to provide parent teaching. Well educated nurses are better able to provide parents with insight regarding the need to continue therapy. The patient to nurse ratio was improved, thus providing more time for nurses to provide individualized parent education. Both the intervention site in Guatemala and the control site in Honduras offered transportation assistance and housing for families as measures to prevent abandonment. In addition, both sites had 2 full time psychologists on staff that provided education to parents. This study suggests that a combined effort of nursing and psychosocial intervention provides the best option for preventing abandonment.

Study Strengths and Limitations

A key strength of the study was the use of logic model theory. Logic model theory facilitated effective program development, implementation, and evaluation and provided a systematic way to present the relationship between interventions and program outcomes. The conceptual model, based on logic model theory, provided a roadmap for the study. The conceptual model illustrated the sequence of program events, beginning with the initial needs assessment and concluded with the intended result at the highest level, the impact on patients with cancer.

An important study strength was the quasi-experimental design used to evaluate the clinical outcomes. The experimental design is the gold standard in research and provides a level of confidence in interval validity that other designs cannot attain. The quasi-experimental design is the second strongest research design. The fidelity of the GNP was also a study strength. If the intervention had not been implemented as designed and well documented the internal validity of the study would have been threatened.

The size and composition of the staff and patient sample were also strengths of the study. Forty-nine nurses met the defining criteria for professional staff nurse and all were included in the study. Pediatric oncology treatment in Guatemala is only available at the IOP partner site, thus the staff nurses included in the study essentially represent the

pediatric oncology staff nurse population for the country. The clinical sample included all patients at IOP's partner sites in Guatemala and Honduras diagnosed with cancer between January 1, 2004 and October 1, 2008 and registered in POND (N = 1, 936). This sample also essentially represented the population of pediatric oncology patients for both countries since pediatric oncology treatment in Guatemala and Honduras is only available at the IOP partner sites. Samples that are this representative of the population add to the external validity of the study.

The detailed documentation available to evaluate staff and organizational outcomes was another positive attribute of the study. According to program theorist Carolyn Weiss (1998) a lack of documentation of program activities is often a limiting factor in program evaluation. In 2006, the quality of nursing care in Guatemala was assessed using standards from six Joint Commission International (JCI) quality domains. The evaluation provided detailed pre program data regarding 20 JCI standards relevant to nursing and was the basis for the post program comparison. Data for staff outcomes were also very well documented. Each of the 49 nurses in the sample had an individual education record that included thorough documentation of the education provided and also included copies of the scored evaluation tests.

The study also benefited from the use of JCI standards as an instrument. The JCI standards were developed by an international task force and have been validated through quality and safety studies by public agencies and ministries of health outside the U.S. (Joint Commission International, 2007). JCI standards were developed for use within a specific population of health care organizations, and included public hospitals in developing countries. The standards take into account that hospitals in many developing countries do not yet function at the level of U.S. hospital standards; therefore, they are less stringent in evaluation criteria (Marshall et al., 2006). The standards have been adapted for the international community and are designed to be culturally applicable and compliant with laws and regulations outside the U.S. (Timmons, 2007). A set of standards this broad in nature cannot account for a country's unique characteristics; however, there is evidence that many quality concerns are universal. Aiken, Clarke, and Sloane (2002) noted that countries tend to believe problems with quality of care and nurse staffing are a result of unique circumstances. Yet, data from their study suggested that contrary to popular opinion, many hospital problems know no country boundaries.

Conducting research in a developing country with limited resources and cultural and language barriers was perhaps the greatest limitation of this study. Clinical endpoints for this research were abandonment of treatment and event free survival rate of children with cancer. Data for traditional nurse-sensitive measures, such as nosocomial infection rates, central venous line and chemotherapy complications, and pain management were not available and was another limitation of this study.

The nurse educator in Guatemala assumed the educator role in January 2007. The Latin American Center for Pediatric Oncology Nursing Education, designed to provide nurse educators with the education, resources, and professional support was not operational until January 2008. The educator did not benefit from the Center's support

initially and this was a study limitation. However, during the educator's first year, the IOP nursing director organized on site education and provided support and direction via bimonthly conference calls.

The GNP experienced changes during the study's 3-year time span which was an additional limitation. In 2008, after the nurse educator completed the educator course at the Latin American Center for Pediatric Oncology Nursing Education, the pediatric oncology nursing education course, the chemotherapy administration course, and the central venous line care course were revised to include expanded content. In addition, the educator matured in his knowledge level and teaching skills during the course of the study.

Staff nurse outcomes, specifically competency in chemotherapy and central venous line care, were measured using assessment instruments developed by the nurse educator in Guatemala. Content validity was assessed by nurse experts from the Latin American Center of Pediatric Oncology Nursing Education. Three nurses reviewed each question for relevance and clarity. The reviewers had access to the courses' content for reference. Revisions to several questions were made based on the review. A limitation to the study was the fact that the instruments had not been rigorously assessed for content validity, and reliability testing had not been done.

Recommendations for Future Research

Nursing research in developing countries is limited, resulting in unique opportunities to conduct many "first time" studies. Today all components of the health care system are expected to demonstrate their value, and accountability is an important expectation of the health care system. This is even a greater need in developing countries where nursing is given little value and support. Nursing policies that dictate patient to nurse ratios and funding of new nursing positions are determined by the Ministry of Health in most developing countries. Empirical evidence is needed to justify changes in policy. Evidence that education and improved staffing impact clinical outcomes has the potential of providing an impetus for a change in nursing policy.

There is a need for further research in developing countries to determine the effects of nursing education and improved nurse staffing on patient outcomes. The effect of nursing education on patient outcomes has been extensively researched in developed countries (Aiken, Clarke, & Sloane, 2002; Elixhauser et al., 2003; Estabrooks et al., 2005). Studies conducted in developing countries to assess the effect of staff education on patient mortality are limited; however, a study in Zambia showed a 6 month training course for nurse midwives was associated with a decrease in early neonatal mortality rates (Chomba et al., 2008). The effect of nurse staffing levels on patient outcomes has also been well researched in developed countries (Aiken, Clarke, & Sloane, 2002; Aiken, Clarke, Sloane, Sochalski, & Silber, 2002; Aiken et al., 2008). This study is the first to evaluate the effect of nurse staffing on clinical outcomes in a developing country.

This study found a statistically significant association between the GNP and the CIN (cumulative incidence) of treatment abandonment within the first year of diagnosis. Because this was the first study that determined a relationship between abandonment of treatment in developing countries and interventions specifically related to nursing further research is needed.

Clinical endpoints for this study were abandonment of treatment and the event free survival rate of children with cancer. Evaluating more nurse sensitive outcomes was not possible because a method to collect these end points was not available. Future studies should include endpoints that are more sensitive to nursing, such as nosocomial infection rates, central venous line and chemotherapy complications, nurse satisfaction, and nurse turnover rates. There is also a need to create valid and reliable instruments to measure nurse sensitive outcomes and establish a database that will house these outcomes.

A logical progression in research would be to replicate this study at other pediatric oncology hospitals in developing countries. Similar nursing interventions have been implemented in El Salvador, Chile, Mexico, and Shanghai and should be evaluated. In addition, a cost benefit analysis to assess the economic justification of the GNP should be done.

The GNP model is not limited to use within pediatric oncology settings. The program's principles could easily be adapted to other subspecialties in developing countries. This would represent an opportunity to replicate the model in a different setting and conduct research to evaluate the outcomes.

The National Institute of Nursing Research supports research that elucidates mechanisms underlying health care disparities and designs interventions to eliminate them. The National Institute of Nursing Research's commitment to eliminate health disparities through nursing interventions is clearly aligned with future research in developing countries and a potential source of funding.

Conclusion

Conducting research in a developing country faces the challenges of cultural and language barriers, limited access to data, and great financial costs. Nonetheless, these challenges are offset by the rewards of serving a population with such enormous needs. Research in a developing country offers a unique opportunity in what is considered a pioneering field. This study was the first to evaluate a nursing program designed to improve nursing education, patient nurse ratio, and quality standards and its impact on staff, organizational, and clinical outcomes in a developing country. This study was broad in scope, beginning with an initial needs assessment and concluding with the intended result at the highest level, the impact on children with cancer. Logic model theory facilitated effective program development, implementation, and evaluation and provided a systematic way to present the relationship between interventions and program

outcomes. The conceptual model, based on logic model theory, provided a practical roadmap for this very complex study.

This study substantiated that prior to GNP implementation a lack of education for pediatric oncology nurses existed in Guatemala and demonstrated that a nurse educator can positively impact staff outcomes related to pediatric oncology education. The GNP also positively affected organizational outcomes. Compared to pre program results, the number of JCI standards met post program increased considerably. In 2006, the patient to nurse ratio was 6 to 8 (average 7) patients per nurse and in 2009, the patient to nurse ratio was 4 to 6 (average 5) patients per nurse.

The study found a statistically significant association between the GNP and an improved CIN of treatment abandonment within the first year of diagnosis. Abandonment of treatment is a critical problem in developing countries. Although many studies have looked at abandonment and its causes, no study has looked at the specific effect of nursing on abandonment. This study did not find an association with improved EFS. However, pediatric oncology patients who abandon treatment die, thus an improvement in abandonment should in time result in improved survival. The statistically significant improvement in CIN of abandonment in Guatemala post GNP represents approximately 20 children who continued with treatment and did not die from abandonment during that time period.

The value of nursing is not recognized in many developing countries. Interviews with medical and administrative leaders from IOP partner sites and assessment results support this conclusion (Day et al., 2008). This study has the potential to impact the professional role and identity of pediatric oncology nurses in Guatemala and affect the extent to which nursing's influence might be measured and valued.

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**APPENDIX A: ST. JUDE INSTITUTIONAL REVIEW BOARD APPROVAL #29
FWA00004775**

October 19, 2009

Sara Day, RN, MSN
INTERNATIONAL OUTREACH

Dear Dr. Day:

RE: **XPD09-179** - Evaluating the Impact of a Nursing Program in Guatemala

This is to certify that, on **October 19, 2009**, the **initial protocol application** submitted to the Institutional Review Board for consideration was reviewed by an IRB member using expedited procedures with respect to the adequacy of protecting the rights and welfare of participants, the use of appropriate methods of securing informed consent, the measures to be taken to minimize risk and the degree of risk relative to the potential benefits of the proposed research.

IRB Review Status: **Approved under 45CFR46.110(b)(1) and 21CFR56.110(b)(1), research categories # 5 and # 7 and pediatric categories 45CFR46.404 and 21CFR50.51 for the period of one year. The consent requirements are waived under 45CFR46.116(2)(d). Waiver of HIPAA authorization is granted under 164.508 and 164.512(i). IRB approval for this study will expire 10/19/2010.** If you have questions or need assistance, please contact the Office of Human Subjects' Protection at 901-595-4357 or email hsp-1@stjude.org.

Kathleen Price, RN, MBA, OHSP Director

New Research: ([Pro00001321](#))

Reminder of Principal Investigator Responsibilities:

As previously signed and certified, approval of this research involving human subjects is contingent upon your agreement:

1. To report to the Institutional Review Board for Human Research (IRB) any adverse effect or research related injuries which might occur in relation to the human experimentation. To read and comply with IRB reporting guidelines.

2. To submit in writing for prior IRB approval any alterations to the plan of human research.
3. To submit timely continuing review reports of this research as requested by the IRB.
4. To maintain copies of all pertinent information related to the research activities in this project, including copies of informed consent agreements obtained from all participants.
5. To notify the IRB immediately upon the termination of this project, and/or the departure of the principal investigator from this institution and the project.

**APPENDIX B: UNIVERSITY OF GUATEMALA INSTITUTIONAL REVIEW
BOARD APPROVAL REF# CE/FM-00120**

FROM : UNOP FAX NO. : 24710963 Jul. 13 2010 08:51AM P1

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Guatemala, 20 de Enero 2,010

Doctor
Federico Antillón-Klussmann
Unidad Nacional de Oncología,
Pediátrica UNOP
Presente.

Estimado Doctor Antillón-Klussmann:

Reciba un atento saludo de nuestro Comité De Ética y deseando que el año que empieza 2,010 le depare prosperidad en sus actividades. El motivo es para comunicarle que el Comité De Ética en su Sesión del 19 de Enero revisó y aprobó el Protocolo Titulado: "Evaluating the Impact for a Pediatric Oncology Program in Guatemala."

Sin más por el momento, quedo de usted.

Muy Atentamente,

 Dr. Edgar López Álvarez
 Secretario
 Comité de Ética

ELA/tp

COMITE DE ETICA
FACULTAD DE MEDICINA
UNIVERSIDAD FRANCISCO MARROQUIN
GUATEMALA, C. A.

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VITA

Sara Williamson Day received a diploma in Nursing from Methodist Hospital School of Nursing and a Bachelor of Science in Nursing from Union University. She was Valedictorian of her class at Methodist Hospital School of Nursing and received the Academic Excellence Award at Union University. She received a Master of Science in Nursing with a focus on Health Care Administration from Union University. She has experience in management, research, nursing education, and program development and evaluation. She has worked at St. Jude Children's Research Hospital for 20 years and is currently the Nursing Director for the International Outreach Program. Prior to this she worked in the Department of Hematology where she served as Director of Patient and Clinical Services. She is the author of 20 publications in peer reviewed medical and nursing journals and 42 abstracts and has presented at national and international conferences. She is a board member of the University of Alabama World Health Organization Collaborating Center and a member of the international board of the Association for Pediatric Hematology Oncology Nurses. In May 2010 she received her Doctor of Philosophy in Nursing from The University of Tennessee Health Science Center.